VOLUME 13 NUMBER 10

Food Drug Cosmetic Law Journal

OCTOBER • 1958

Fundamental Progress of the Pure-Food Law . . . . CHARLES WESLEY DUNN

The New Food-Additives Law . . . . GEORGE P. LARRICK

Establishing Tolerances for Food Additives . . . . . WINTON B. RANKIN

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A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

October, 1958
Volume 13 • Number 10

Second-class postage paid at Chicago, Illinois.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

Three papers delivered at a recent meeting of the American Chemical Society, held in Chicago, are featured in this October JOURNAL. The first of them is derived from a speech discussing the food-additives amendment of the Federal Food, Drug, and Cosmetic Act. In it, **Charles Wesley Dunn,** president of The Food Law Institute, Inc., and chairman of our editorial advisory board, notes that this new enactment "marks the most important advance of our national pure food law, in its entire history."

The other two papers were presented by Commissioner of Food and Drugs **George P. Larrick** and by **Winton B. Rankin,** assistant to the Commissioner. Biographical statements concerning these two outstanding representatives of the United States Department of Health, Education, and Welfare may be found in the September, 1958, and January, 1958 issues of the JOURNAL, respectively.

Mr. Larrick's contribution delineates the broad obligations which the new amendment places on government and industry. The paper by Mr. Rankin sets forth procedures for clearance of additives under the enactment; he gives examples of additives whose use should be cleared, lists the pertinent information which petitions should contain, and outlines appeals machinery.

Donald D. Stark—writer of "Parts per Million of What?"—describes the problem of establishing tolerances for permissible residual pesticides under the Miller Amendments to the Federal Food, Drug, and Cosmetic Act. He analyzes the nonaqueous and "as is" bases for establishing such tolerances.

Mr. Stark, of Corona, California, is a partner in the law firm of Clayson, Stark & Rothrock. His paper is derived from a speech which he delivered before the August 26 meeting of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law of the American Bar Association, held at the University of Southern California School of Law, University Park, Los Angeles.

Another of the ABA papers is written by **Edwin L. Harding,** who has been counsel for the Kellogg Company for more than 20 years. He is a member of the Michigan, the District of Columbia and the Illinois bars, and serves on the Lawyers' Advisory Committee of The Food Law Institute, Inc. Mr. Harding is secretary of the ABA section at which he presented his address. In it, he outlined the important scientific activities of the Food and Drug Administration, noting that these activities have not received much discussion at bar meetings. He made special mention of pioneer investigations made by the Administration.

Thomas W. Christopher, associate dean and professor of law at Emory University Law School, Atlanta, Georgia,

in the third paper from the ABA meeting suggests a plan by which more control in food and drug matters would be shifted to the states. This would be accomplished by agreement between the federal government and the states. He notes that "if the states would do their duty and if the consumer could trust them, there would be less need for control from the national capital—at least in some areas."

Mr. Christopher is, at present, visiting professor of law at the University of California Law School, at Berkeley. A member of the Georgia and the Alabama bars, he was at one time a member of the Tuscaloosa, Alabama law firm of Phifer & Christopher.

Also in this issue are the following continuing features: "Christopher Comments," contributed by Professor Christopher; "The Scientists' Forum," written by **Bernard L. Oser,** director of Food and Drug Research Laboratories, Inc., New York City; and "Foreign Law Comment," presented by **Julius G. Zimmerman,** an attorney, also of New York City.

Food-Industry Investigation

The Federal Trade Commission has adopted a resolution directing an investigation and study of the food industry. The investigation is directed toward the integration and concentration of economic power at the retail level of distribution in the industry. The text of the resolution follows:

"Whereas, a substantial percentage of all antimonopoly investigations by the Federal Trade Commission is of alleged violations of law by parties in the food industry; and

"Whereas, the Commission has received many complaints that in the evolution of food distribution in recent years there have developed tendencies to concentration of economic power, to collusive price action and to unfair competitive methods; and

"Whereas, there is broad public interest in preserving competitive free enterprise in the food industry and in preventing unfair methods of competition in that industry; and

"Whereas, it appears to the Commission that, for the reasons stated herein, and for the purposes set forth in Section 6 of the Federal Trade Commission Act, an investigation of the food industry by the Federal Trade Commission would be in the public interest;

"Now, therefore, be it resolved that the Commission in the exercise of the powers vested in it by Sections 6 and 9 of the Federal Trade Commission Act, and with the aid of any and all powers conferred upon it by law and any and all compulsory processes available to it, do forthwith proceed to investigate and study the integration and concentration of economic power at the retail level of distribution in the food industry, which investigation and study shall include consideration not only of the organization, business, conduct, practices, and management of corporations engaged in commerce and which sell food products at the retail level of distribution but shall also include investigation and study of corporations operating as wholesalers, manufacturers, distributors, brokers, or otherwise concerned with the distribution of food products in commerce to the extent that a consideration of their organization, business, conduct, practices, and management is relevant and pertinent to the aforesaid investigation and study."

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Vibrators Seized on False-Claim Charges.—In its September report on enforcement and compliance, the Food and Drug Administration announced seizures of five makes of vibrator devices—all claimed to reduce weight. In addition, three of the vibrators were claimed to prevent or cure arthritis, rheumatism and bursitis. The Administration emphasized, in its announcement, that it is illegal to promote such devices as weight reducers and as cure-alls for disease.

Malcolm R. Stephens, FDA's Director of Enforcement, said that sales of the machines—from small cushion-type models to large upholstered chairs—are booming, and some promoters apparently feel that they must indulge in false or misleading therapeutic claims in order to keep sales up. According to Mr. Stephens:

"Vibrators make up the major part of our cases against misbranded devices. We believe they can and should be sold on the basis of truthful statements, without resort to false claims for reducing weight, eliminating worry, and alleviating disease conditions."

Seizures of five other vibrator devices in six court actions had been reported in August by FDA.

According to expert medical opinion, benefits of the devices are limited to *temporary* relief from *minor* physical conditions. Also, such cushions, machines and chairs may be soothing and relaxing to the user and help to relieve minor aches and pains due to fatigue or overexertion. However, one machine promoter claimed that his device would relieve menstrual cramps, backaches, headaches, hypertension, and nervous tension of the heart. Another gave this explanation of his reducing technique:

"The vibration in areas where it is applied breaks up fatty deposits so that they can be carried off with other wastes, firmed, and redistributed."

All but one or two cases brought so far in the FDA seizure drive have resulted in relabeling of the devices with false claims eliminated.

Administration Removes Unfit Seafood from Market.—During the hot weather, the Food and Drug Administration kept a closer check on seafoods and other perishables. During August alone, more than 15 tons of fish were removed from the market, in seizures from ten suppliers.

Spoilage, parasitic cysts, and insanitary packing conditions were alleged

in the federal court actions. Fish sticks and fish-breading material were also seized on the basis of alleged insect contamination and insanitary plant conditions.

Voluntary Corrective Actions by Food and Drug Firms.—According to reports by FDA inspectors, food firms voluntarily destroyed or converted to animal feeding or nonfood use more than 157 tons of unfit foods during the month of August. Drug plants voluntarily destroyed old and substandard drugs valued at $22,278. Food establishments spent an estimated $19,050 on plant improvements to remedy conditions pointed out by inspectors.

In the previous month, inspectors had reported plant improvements in food establishments estimated to cost $261,623. Some involved simple changes costing a few hundred dollars; others involved complete plant renovations costing many thousands of dollars.

Vacuum Cleaners—Seizure for Infectious-Disease Claims. — Twenty-eight vacuum cleaners manufactured by a Chicago firm were seized recently by FDA. The Administration pointed out that any article may become subject to the Federal Food, Drug, and Cosmetic Act if therapeutic claims are made for it.

In this case, sales literature claimed that by filtering the air in a home, the canister-type cleaner would prevent streptococcic infections of the sinuses, lungs, joints, etc., and such diseases as tuberculosis, scarlet fever, diphtheria, erysipelas, peritonitis, angina, bronchopneumonia, meningitis, pleurisy, mastoiditis, septic sore throat, arthritis, smallpox, measles, anthrax, tetanus, whooping cough, enteritis, asthma, and skin and lung diseases.

Under the terms of a consent decree of condemnation, the firm destroyed the literature and agreed to sell the cleaner in the future without therapeutic claims.

Notice Concerning Apple Pomace Containing Excessive Residues.—Apple pomace containing more than 7 parts per million of DDT is unsuitable for use in animal feeding, the Food and Drug Administration said in an official notice to farmers, feed merchants and feed manufacturers, the Administration announced on October 18.

Under the food-additives amendment to the Federal Food, Drug, and Cosmetic Act, it will be illegal for a processed food or feed to contain more residue of a pesticide than is allowed on the raw product from which it is made, unless a higher tolerance has been granted for the final product. The tolerance for DDT on apples is seven parts per million.

At the same time, FDA cautioned that apple pomace containing DDT in any quantity is not suitable for dairy feeding and that it involves risk of producing illegal meat if fed to meat animals, even though the pomance contains DDT in lower concentrations than seven parts per million.

No DDT is permitted in milk, FDA said. Studies show that even minute amounts of DDT in feed will result in contaminating milk with this pesticide.

A tolerance under the law permits seven parts per million of DDT to remain in or on the fat of meat from cattle, sheep and hogs, according to FDA. However, the agency pointed out, animals consuming DDT may accumulate considerably more of it in their fat than was present in the feed, because DDT is stored and accumulated in fat tissue. Once the DDT content of the animal fat exceeds the tolerance, a long period on DDT-free feeding may be required to reduce the excessive residues to the permissible level.

It has not been established, FDA stated, under what conditions of feeding, if any, apple pomace containing less than seven parts per million of DDT can be fed to animals without causing the meat from them to contain excessive DDT residues. Unless a producer is in a position to establish this, he should not use apple pomace in feeding meat animals, the agency advised.

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Vol. 13, No. 10 October, 1958

Food·Drug·Cosmetic Law
Journal

Fundamental Progress of the Pure-Food Law

By CHARLES WESLEY DUNN

Mr. Dunn—Addressing the Division of Industrial and Engineering Chemistry, American Chemical Society, in Chicago September 11—Outlines Reasons for the Food-Additives Amendment, and He Offers a Summary Explanation of It

"WE HAVE RECENTLY NOTED[1] that two historic trends dominate the modern progress of the pure food law, in its broad national and international conception. The first trend is for an advance safety regulation of chemical food additives, by one plan or another. This trend is caused by the increasing use of chemicals in manufactured food, to preserve or improve it; and by the increasing development of agricultural pesticide chemicals, which leave residues in natural food. Whereas the second trend is for a uniform pure food law; and it is caused by an industrial need for such a law, to provide a common regulation of food sold in different markets. That trend is strikingly illustrated by the current scientific action for a uniform food code in Latin America and Western Continental Europe, respectively; and by the continued general action in our country for uniform federal and state food laws. You are referred to our previous examination of it at this meeting of the American Chemical Society.[2]

"[1] In a paper read in Symposium IV on foreign food additives by the International Commission for Agricultural Industries and the Permanent International Bureau of Analytical Chemistry in Paris on July 17, 1958.

"[2] In a paper read at the morning meeting of the Division of Chemical Marketing and Economics of the American Chemical Society in Chicago on September 11, 1958."

The Author—Who Heads The Food Law Institute and the Division of Food, Drug and Cosmetic Law, American Bar Association—Is General Counsel, Grocery Manufacturers of America, Inc.

"This paper will review the first trend to the extent of discussing the food additives amendment of the Federal Food, Drug, and Cosmetic Act [3] (hereinafter called the FDC Act), just enacted on September 6, 1958; which is administered by the Secretary of the United States Department of Health, Education, and Welfare, through its Food and Drug Administration (hereinafter called the FDA) directed by a Commissioner of Food and Drugs. For this amendment requires an industrial safety pretesting of food additives that are potentially unsafe, as provided, to determine whether they are actually safe under the conditions of their intended use. The purpose of this amendment is thus to protect the public health; and also to authorize beneficial progress in food technology by permitting the use of essential or valuable food additives at safe levels, which are otherwise unsafe. This amendment also has the additional incidental purpose of establishing a federal standard for analogous state (including municipal) legislation.

"The great significance of this amendment is indicated by saying that it marks the most important advance of our national pure food law, in its entire history; and that it is a law which has fundamental protective significance to both the consuming public and the food and chemical manufacturing industries alike. Moreover its industrial pretesting law (as such) is unique in the annals of pure food legislation, in its international comprehension.

I

"Our discussion of this amendment should begin with the following background statement. It replaces the FDC Act's original basic

[3] The text of the amendment appeared in the September, 1958 JOURNAL, beginning at p. 549.

law against unsafe food additives. That law prohibited any food additive which is a poisonous or deleterious substance, except where it is required in the production of food or cannot be avoided by good manufacturing practice; in which event it may not exceed a maximum safety tolerance administratively established. However this exception became inoperative in the course of time. For it was principally designed to deal with pesticide chemical residues in natural food, which a 1954 amendment of the FDC Act regulates; and administrative experience disclosed no manufactured food additive that met its strict conditional test. Hence such law was thus converted into an absolute one.

"But while that old law was strong to the extent it so absolutely prohibited any manufactured food additive which is a poisonous or deleterious substance, it did not adequately protect the public health. For in the vital area of its enforcement it was an *ex post facto* law that did not reach an unsafe additive in such food, until it was sold and injuriously consumed. Whereas its enforcement should reach the additive, before then; and this can only be done by substituting an industrial safety pretesting law. Further that old law placed the burden on the government to prove that such a food additive is a poisonous or deleterious substance; and proof of this fact might require at least two years of scientific laboratory investigation, during which no enforcement action could be instituted against the additive's use in or on food. Whereas a substitute industrial safety pretesting law rightly places its burden on the manufacturer of such an additive or of a food bearing or containing it.

"Moreover that old law was scientifically unsound in thus absolutely prohibiting any manufactured food additive which is a poisonous or deleterious substance, because it may be essentially or valuably used at a safe level; and by doing so the law prevented beneficial progress in food technology, which is in the public interest and may be necessary to protect the public health. Such law unsuccessfully attempted to recognize this fact, through its aforementioned exception to authorize administrative safety tolerances; and the FDC Act's 1954 amendment squarely does so. For it regulates pesticide chemicals whose agricultural usefulness has been certified by the United States Department of Agriculture, by prohibiting any residue therefrom in or on a raw agricultural commodity (such as a fruit or vegetable) unless its quantity is within the limits of a maximum safety tolerance administra-

tively established; or unless the chemical is one that has been administratively exempted from such a tolerance. It may be noted here that we suggested this amendment in a paper to the Division of Agricultural and Food Chemistry of the American Chemical Society at its 1948 meeting in Chicago.

2

"For these reasons Congress began an investigation of that old law for its due amendment, which the FDA suggested. This was a broad investigation of chemical food additives; and it was first made by the House Delaney Committee in 1950-1952, through public hearings. The Committee thereafter recommended that the FDC Act be amended to require an industrial safety pretesting of such additives, analogous to that required for new drugs. This recommendation achieved the following results: Congress enacted the foregoing 1954 amendment of this Act to provide for the safety of pesticide chemical residues in natural food; numerous House bills were introduced for an amendment of this Act to require an industrial safety pretesting of manufactured food additives in general and chemical ones in particular, including an administration bill (H. R. 6747, 85th Congress, 1st Session); and the House Commerce Subcommittee on Health and Science then instituted comprehensive public hearings on them, which began in 1956 and ended on April 15, 1958 and mainly dealt with chemical additives in food.

"The outcome was that the House Commerce Subcommittee unanimously reported the administration bill in a revised form on July 1 last, which was then reintroduced as a clean bill (H. R. 13254, 85th Congress, 2d Session); the House Commerce Committee unanimously reported that bill on July 28 and thereafter added a Delaney cancer amendment later explained; the House unanimously passed that amended bill on August 13; the Senate Labor and Public Welfare Committee unanimously reported such bill on August 18, with an amendment increasing the annual salary of the FDA Commissioner from $17,500 to $20,000; the Senate unanimously passed this amended bill on August 23, with an amendment relating to the Poultry Products Inspection Act later explained; the House unanimously concurred in these Senate amendments on August 23; and the President approved the bill thus passed by Congress on September 6, when it became a law.

"This is briefly the legislative record of the amendment before us and we now make the following comments on it: while this amend-

ment has a broad food additive application as we shall see, it is principally designed to regulate chemical food additives; the FDA drafted the original administration bill for it; the Congressional revision of this bill was mainly suggested by the food and chemical manufacturing industries; the House and Senate reports on and discussions of the revised bill contain valuable interpretative statements; and its unanimous Congressional enactment was a remarkable legislative accomplishment. For while there was a general agreement on the protective need of such an amendment, its form was a highly controversial question in significant details; and this question was only resolved after its thorough discussion for about eight years and by a final compromise accommodation of conflicting FDA and industrial views. This situation illustrates the fact that controversial public legislation by a democratic government, under which there is freedom of opinion and differences in it, is normally enacted on a more or less compromise basis; the concern is to make sure that such compromise is a sound and just one in the circumstances; and that result was achieved in enacting this amendment.

"We should go on to record the names of the Congressional leaders who were principally responsible for the enactment of this historic amendment. They are Representative James J. Delaney, who sponsored the original House investigation for it; Representative A. L. Miller, who long worked for it; Representatives J. Percy Priest (deceased) and John Bell Williams, who chaired the House Commerce Subcommittee's hearings for it; Representative Oren Harris, who as Chairman of the House Interstate and Foreign Commerce Committee directed its House report and passage; and Senator Lister Hill, who as Chairman of the Senate Labor and Public Welfare Committee directed its Senate report and passage. But the major credit for this amendment goes to the FDA (represented by Commissioners Dunbar, Crawford and Larrick and Deputy Commissioner Harvey), which recommended it and unceasingly labored for it with strong help by Assistant Secretary Elliot L. Richardson of the United States Department of Health, Education, and Welfare. Furthermore due tribute should also be paid to the consumer, scientific and industrial organizations, which influentially supported this amendment; and especially to the major national associations of the food and chemical manufacturing industries, which responsibly and effectively cooperated for its final enactment. I am deeply proud of the fact that the Grocery

Manufacturers of America, Inc., the overall national association of food manufacturers for which I am general counsel, advocated this amendment from its beginning in the Delaney Committee hearings and constructively acted for its final enactment in a due form.

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"Having thus outlined the reasons for and the record of the amendment before us we come to a summary explanation of it, conveniently organized and practically stated. For it is a long and technical amendment, containing numerous sections and mounting to six printed pages. And in making this explanation we have recognized interpretative comments by Congress.

"The amendment first correctly provides that its citation name is 'Food Additives Amendment of 1958'; and it next broadly defines the term 'food additive', subject to certain exemptions. This definition conforms with the general pattern established by the FDC Act's prior definitions of a new drug and a pesticide chemical, respectively; and it should be approached from the standpoint that a food additive is also a food within the meaning of this Act. Consequently we must recall the Act's definition of that basic term.

"As so defined and subject to the foregoing exemptions a food additive is here any old or new substance (whatever it may be and including any source of radiation, such as radioactive isotopes, particle accelerators and X-ray machines) intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding a food (including a drink) for human or animal consumption, which results or may reasonably be expected to result in its becoming a component or otherwise affecting any characteristic of such food, either directly or indirectly, if it is a substance that is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (including a review of the existing and related scientific literature) to be safe (referring to the health of man or animal, respectively) *under the conditions of its intended use,* or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food.

"This is a rather long and somewhat complex definition, which may be clarified by the following practical restatement of it. Subject to the exemptions later noted a food additive regulated by this amend-

ment is principally any old or new substance aforesaid (especially a chemical one) intentionally (as distinguished from accidentally) and directly (as distinguished from indirectly) added to a human or animal food (including a drink) in its production or manufacture (etc.) for commerce regulated by the FDC Act, which is potentially unsafe under the conditions of its actual or intended use (including any change therein). This question must be scientifically determined as provided, if it has not instead been determined by the experience of common use in the case of old food additives used before January 1, 1958. As to a substance thus accidentally added to a food, it remains regulated by the Act's existing prohibition of a food that bears or contains any poisonous or deleterious substance which may render it injurious to health. An example of such an accidental additive is a residue contamination of food, resulting from the use of a paint or cleaning fluid in the factory where it was manufactured. But this amendment applies to any potentially unsafe substance indirectly added to a food in its aforesaid production or manufacture or through its packaging or because of the conditions under which it is held or transported, where such addition may reasonably be expected. That is a question of fact to be appropriately determined in each instance. Hence the responsibility to prevent such an indirect additive extends to all who hold or transport a food in the course of its distribution within the jurisdiction of this Act.

"We suggest that the administrator of this amendment initially publish an advisory list of the food additives he deems subject thereto, to the extent this action is feasible and does not violate a trade confidence or reveal a trade secret protected by the FDC Act; and that its publication be progressively continued hereafter, to the same extent. We also suggest that he likewise publish an advisory list of old food additives excluded from this amendment by the experience of their common use, to the same extent. The provision relating to that experience is a further appropriate standard to determine the safety of such additives. We should go on to note: it has already been administratively said that this standard applies to many old food chemicals, such as salt, sugar, vinegar and baking soda, whose safety has been established by long feeding to generations of human beings; and it has also been administratively said that this standard applies to the use of a food additive by a single manufacturer, whose safety has been established by its long use.

"The amendment before us then exempts five food additives from its regulation, on a class basis. They are:

"(*1*) Any pesticide chemical in or on a raw agricultural commodity, which is otherwise regulated by the FDC Act. This exemption also reaches any pesticide chemical intended to be used in the production, storage or transportation of such a commodity.

"(2) Any substance used in or on a food in accordance with a sanction or approval granted pursuant to the FDC Act, prior to the enactment of such amendment on September 6. This exemption principally applies to chemicals then administratively permitted by definitions and identity standards for food; and we suggest that the administrator publish an advisory list of them. But this exemption further applies to chemicals then otherwise administratively permitted in or on food; and we suggest that the administrator likewise publish an advisory list of them, to the extent such action does not violate a trade confidence or reveal a trade secret protected by this Act. We should go on to say that the administrator may hereafter modify or revoke his prior approval of any food additive, as authorized by the amendment before us.

"(*3*) Any substance used in or on a meat or a meat food product in accordance with a sanction or approval granted pursuant to the Federal Meat Inspection Act, prior to the enactment of such amendment on September 6. This exemption principally applies to chemicals then permitted in or on such food by the Secretary of the United States Department of Agriculture, who administers that Act; and we suggest that he publish an advisory list of them. He may hereafter modify or revoke his prior approval of any meat additive, in due course. This amendment goes on to provide that nothing herein shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Federal Meat Inspection Act. And Congress made the following comment on that provision: it leaves unaffected that Department's jurisdiction over the use of food additives in meat or meat food products in establishments which are subject to the Federal Meat Inspection Act. We should here recall the basic exemption reference to that Act in the FDC Act. It is that meats and meat food products shall be exempt from the provisions of the latter Act to the extent of the application or extension thereto of the Federal Meat Inspection Act.

"(*4*) Any substance used in or on a poultry food product in accordance with a sanction or approval granted pursuant to the Federal Poultry Products Inspection Act, prior to the enactment of such amendment on September 6. This exemption principally applies to chemicals then permitted in or on such a product by the Secretary of the United States Department of Agriculture, who administers that Act; and we suggest that he publish an advisory list of them. We should go on to say that this exemption was added by the Senate; and that it invites the comments made on the preceding exemption relating to the Federal Meat Inspection Act, to the extent they are applicable.

"(*5*) Any food additive and any food bearing or containing it that is intended solely for investigational use by qualified experts, which are administratively exempted from the requirements of such amendment. Its administrator is directed to make this exemption by regulation, when in his opinion it is consistent with the public health.

"We should note here that this amendment likewise does not apply to food additives which are coal-tar colors, because they are regulated by a traditional separate law of the FDC Act. It prohibits a food which bears or contains a coal-tar color other than one from a batch administratively certified; and its administrator is then directed to list coal-tar colors which are harmless and suitable for use in food and to certify batches of them, with or without harmless diluents. This law contains some citrus fruit exemptions; and it now invites two comments. The first comment is that it is administratively construed not to authorize maximum safety tolerances for its coal-tar colors; and that the United States Supreme Court will soon decide whether such construction is right. We hope the Court will decide that this law does authorize such tolerances. For it should do so, in principle and because a tolerance must be zero where required to protect the public health; there will then be no need for its amendment to grant that authority; and it would then conform with the general food additive amendment before us and with the supplemental pesticide chemical additive amendment, which each authorize similar tolerances.

"This statement leads directly to the second comment. It is that the coal-tar color industry caused the introduction of a bill (H. R. 8945) in the last Congress, which (*inter alia*) amends the above food coal-tar color law to authorize such tolerances. But the amendment will become unnecessary, if the Supreme Court decides that this law does authorize such tolerances; whereas if the Court decides otherwise the law is better amended to bring its coal-tar color additives under the adequate protective regulation of the foregoing general food addi-

tive amendment, with their batch certification maintained. Furthermore the bill is also objectionable, because and to the extent it broadens this food coal-tar color law to similarly regulate other food colors, except as provided. For they are now subject to the adequate protective regulation of such general food additive amendment; and consequently the only question remaining here is whether or to what extent their batch certification should likewise be required.

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"The amendment before us next provides that a subject food additive or a food bearing or containing it is adulterated within the meaning of the FDC Act and therefore outlawed from interstate and foreign commerce, if it is unsafe within the meaning of new section 409 then written into this Act; and that provision became effective when the amendment was enacted on September 6, except as later noted. Hence the foregoing section contains the basic regulatory law of this amendment; and we emphasize that it applies to both any such additive and any food bearing or containing it.

"But our explanation of this law should be preceded by three related comments. The first comment is that this amendment further revises the Act in two collateral respects. For on the one hand this Act is revised to prohibit any intentional radiation of food, unless its use conforms with an administrative regulation or exemption pursuant to new section 409. Whereas on the other hand this Act is revised to provide that where a pesticide chemical has been used in or on a raw agricultural commodity, in conformity with an administrative exemption or tolerance, its residue in or on a food processed from this commodity shall not be deemed unsafe, if it has been removed to the extent possible in good manufacturing practice and its concentration in that food when ready to eat does not exceed such tolerance.

"The second comment is that this amendment is enforced by the criminal and seizure and injunction proceedings authorized by the FDC Act; and in each proceeding the government has the burden of proving a violation of the amendment to the required degree. The third comment is that such enforcement jurisdictionally follows a subject food additive or a food bearing or containing it which has been shipped in interstate commerce, down through each sale thereafter in intrastate commerce. But where such additive or food is intended for export it is not adulterated or misbranded under the FDC Act, if *(1)* it accords with the specifications of the foreign purchaser, *(2)* it is not in conflict with the laws of the country to which it is intended for

export, and *(3)* it is labeled on the outside of the shipping package to show that it is intended for export. From the standpoint of that export exemption this amendment is weaker than the Act's new drug law, because it is not subject thereto. Congress should review this serious defect.

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"Turning now to the basic regulatory law of the amendment before us, contained in new section 409, and recalling that it applies to old and new food additives which are potentially unsafe as and to the extent previously explained: This law provides that any such food additive is unsafe within the meaning of section 409 and therefore outlawed from interstate and foreign commerce as aforesaid, unless its actual or intended use conforms with an effective administrative regulation issued thereunder prescribing the conditions under which it may be safely used. The law is then procedurally divided into two parts, for establishing such a regulation by an administrative order. The first and major part is an industrial safety pretesting law, which is analogous to the new drug law of this Act; it is a long and elaborate law hereinafter described; and it will not become effective until later, as we shall explain. Whereas the second part is a supplemental administrative safety control law, which has no counterpart in the new drug law; it became immediately effective on September 6, when this amendment was enacted; and because it is a short law, we may quickly describe it now. That law broadly authorizes its administrator, upon his own initiative and at any time, to propose and, thirty days after its publication, to establish a regulation, with respect to any particular use of a subject food additive, prescribing the conditions under which it may thus be safely used and stating the reasons for such regulation. It is in the nature of a special regulation, for establishment if and when it is required to protect the public health. For example: where an old food additive previously deemed safe is later found to be unsafe under the conditions of its use; as in the case of coumarin, dulcin and nitrogen trichloride (Agene). In short: that administrative safety control law should be approached from the standpoint that it supplements the major industrial safety pretesting law; but from this standpoint there is no limitation on its due protective use. It should be recalled here that the administrator of this Act is now authorized forthwith to proceed against any food that bears or contains any poisonous or deleterious substance, which may render it injurious to health.

"We should now go on to say: an administrative order establishing such a regulation under either aforesaid law is effective upon its publication, unless it is administratively stayed for its authorized review; the regulation may be administratively amended or repealed for cause shown, by a procedure administratively determined and conforming with that for the regulation's establishment; and it is subject to an optional administrative and judicial review, which is required by the Administrative Procedure Act and follows the traditional general pattern of such a review under the FDC Act. The administrative review is made through a public hearing, requested by a person adversely affected by an administrative order for the regulation in issue; and the judicial review is of the administrative order made after such hearing, which is instituted by a person adversely affected and is initially made by the United States Court of Appeals. But this review is subject to the following important comment. The order made after the administrative hearing must be based upon a fair evaluation of the entire hearing record; and the Appeals Court may not sustain this order unless it complies with that fair evaluation requirement. In enacting the amendment before us Congress said that this requirement is a new standard of judicial review under the FDC Act, which differs from the standard of 'substantial evidence on the record as a whole' that has heretofore been the criterion under this Act. The House Committee report on this amendment said: 'The committee feels that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possible equal or even greater substance.' And in its report on this amendment the Senate Committee quoted the following explanatory statement made by the chairman of the House Subcommittee which revised and reported the bill for it: 'Manufacturers of food and of food additives have manifested concern that under an administrative type of control over the use of food additives, such as is provided by H. R. 13254, it would be possible for the institutional decisions of the Secretary of Health, Education, and Welfare to be based, for example, more upon the personal convictions of scientists employed by the Food and Drug Administration regarding the safety of an additive than upon the inferences fairly to be drawn from the scientific evidence of record. H. R. 13254 provides that orders regarding the use of food additives must "be based upon a fair evaluation of the entire record." The committee has endeavored to prescribe a

new statutory criterion requiring that a high standard of fairness be observed in administrative rulemaking under this bill. Personal attitudes or preferences of administrative officials could not prevail on the basis of being supported by substantial evidence picked from the record without regard to other evidence of probative value in the record. The United States Courts of Appeals will be able to enforce this high standard by determining whether the Secretary of Health, Education, and Welfare has given appropriate consideration to the inferences which should fairly be drawn from all of the evidence of record.'

"We should further note here that the administration bill for this amendment also originally provided for an optional scientific review of any regulation authorized by it, similar to that now provided by the pesticide chemical law of the FDC Act. It was a review of a proposed or published regulation upon industrial or administrative request, made by an *ad hoc* expert and qualified scientific advisory committee selected by the National Academy of Sciences. But the House Commerce Committee eliminated this additional review, because of certain industry objection to it. We regret its elimination, because it provided another and perhaps needed opportunity to reverse or modify a scientifically unwarranted regulation under the amendment before us; and the only parties injured by its elimination are members of the food and chemical manufacturing industries, who might have desired such review. For the administrator of this amendment is now free to secure expert and qualified scientific advice on its administration, where it is desired; as Congress noted in its reports thereon.

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"We have finally to examine the major part of this basic regulatory law in new section 409, which (as hereinbefore stated) is an industrial safety pretesting law to establish an administrative regulation that prescribes the conditions under which a subject food additive may be safely used. This law does not become effective until the one hundred and eightieth day (or six months) after September 6, when the amendment before us was enacted. But such postponement is further extended for any particular commercial use of an additive before January 1, 1958. This extension is either for one year after that one hundred and eightieth day or for an additional period (not exceeding another year thereafter) administratively prescribed for cause or until an administrative order becomes effective with respect

to said use of the additive, whichever date occurs first. The foregoing postponement, taken as a whole and broadly speaking, is practically required in the circumstances. But such law may and therefore should be voluntarily complied with during this transition period, where industrially permitted; and that statement leads to the following comment. We advise that manufacturers of food bearing or containing chemical additives should forthwith make a precautionary scientific inventory of them, from the standpoint of this law and due compliance with it.

"This law has precisely the meaning its name indicates. For it is a law that requires an adequate industrial safety pretesting of any old or new food additive which is potentially unsafe, as previously explained, to determine whether it is safe under the conditions of its actual or intended use. The term 'safe' here means that the additive is not hazardous to the health of man or animal, depending on whether it is used in food for human or animal consumption. Moreover in its reports on the amendment under review Congress said: 'Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance. . . . In determining the "safety" of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use. Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.'

"We also refer to the later statement of the relevant safety factors which the administrator of this law must consider, in determining whether the use of an additive is safe.

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"The responsibility for complying with this industrial safety pretesting requirement, in the case of a subject chemical food additive for example, first normally resides in the manufacturer of such an additive intended for commerce regulated by the FDC Act; and it then also resides in the manufacturer of a food bearing or containing

this additive, intended for such commerce. But the latter food manufacturer may and therefore should obtain a guaranty from the former additive manufacturer, authorized by this Act, that a food bearing or containing his additive is not adulterated or misbranded within the meaning of this Act when it is used as directed by him. For if a food manufacturer obtains such a guaranty in good faith from a responsible chemical additive manufacturer and uses his additive as thus directed, it is a legal defense against a criminal prosecution of the former manufacturer as provided by this Act for so using the additive. But if the food manufacturer significantly deviates from such directed use of the additive or if he independently develops his own use of this or another chemical additive, he is subject to the safety pretesting requirement of this law. We should note here that such a guaranty is not a legal defense against a seizure or an injunction proceeding under this Act: and that a food manufacturer remains free to confirm the safety pretesting of an additive covered by such a guaranty.

"This law then provides that after the manufacturer of a subject food additive or the manufacturer of a food bearing or containing it, as the case may be, completes its required safety pretesting, he must file a petition with the administrator regarding it. This is a petition that proposes the issuance of an administrative regulation prescribing the conditions under which such additive may be safely used; and that contains specified data later described. The administrator is directed to publish the regulation proposed by such a petition, in general terms, within thirty days after it has been filed. This petition should not be filed unless the pretesting of its additive adequately shows that it is safe for use under the conditions of its intended use; the law does not require that the petition submit a formal draft of the regulation thus proposed, but there is no provision against its doing so; and the petitioner may discuss the proposed regulation with the FDA, in their mutual discretion. We suggest that the administrator of this law develop a printed form of such petition, which contains full instructions for its use, as is done in the case of an application under the new drug law of the FDC Act. We should go on to say that the amendment before us prohibits any administrative misuse of information secured under this law about a method or process which is entitled to protection as a trade secret; and any administrative disclosure of such information other than in the due administration of this Act or when relevant in a judicial proceeding thereunder.

"Such a petition must contain, in addition to any other explanatory or supporting data voluntarily submitted: *(1)* The name and all pertinent information concerning the additive in question, including (where available) its chemical identity and composition; *(2)* a statement of the conditions of the additive's proposed use, including all directions and recommendations and suggestions proposed for its use and also including specimens of its proposed labeling; *(3)* all relevant data bearing on the physical or other technical effect which the additive is intended to produce, and the quantity of it required to produce this effect; *(4)* a description of practical methods for determining the quantity of the additive in or on food, and any substance formed in or on food because of its use; and *(5)* full reports of investigations made with respect to the additive's safety for use, including full information as to the methods and controls used in conducting these investigations. Moreover, upon request by the administrator, the petitioner must furnish (or, if the petitioner is not the manufacturer of the additive in question, he must have its manufacturer furnish without disclosure to him) a full description of the methods used in, and the facilities and controls used for, the production of the additive. Further, upon request by the administrator, the petitioner must also furnish samples of the food additive in question, or articles used as its components, and of the food in or on which the additive is proposed to be used. We should go on to say here that the administration bill for the amendment under review originally required that the petition report all relevant data bearing on the functional value of the additive in question; and that it authorized the administrator to take its functional value into consideration, in approving the use of an additive which is a poisonous or deleterious substance. But the House Commerce Committee eliminated these provisions and substituted those in foregoing clause *(3)*.

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"This law next requires its administrator first to fairly evaluate the pretesting and further data submitted by such a petition for an administrative regulation on a food additive, together with any other relevant data before him; secondly to issue an order, within ninety days after the petition was filed unless this time is administratively extended for a period not exceeding an additional ninety days, which either denies the petition or establishes a regulation prescribing the conditions under which the additive may be safely used; and thirdly

to forthwith notify the petitioner of such order and the reasons for it. Any person adversely affected by the order may thereafter secure the administrative and judicial review previously explained.

"The law then defines four standards governing the administrative issuance of this regulation for a food additive. The first standard is that no such regulation shall issue if the administrator's fair evaluation of all the relevant data before him either *(1)* fails to establish that the proposed use of the additive will be safe, under the conditions to be specified in the regulation; or *(2)* shows that such proposed use of the additive would promote deception of the consumer in violation of the FDC Act or would otherwise result in the adulteration or misbranding of food within the meaning of this Act. The House Committee added the following proviso to the first part of this standard, requested by Representative Delaney: no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal after tests which are appropriate for evaluating the safety of food additives. In its report on the amendment before us the Senate Committee made this comment on that proviso: the amendment would mean the same with or without such proviso. For it is designed to assure that nothing shall be added to food which can reasonably be expected to produce any type of illness in man or animal.

"The second standard is that if in the administrator's judgment, based on a fair evaluation of the relevant data before him, a tolerance limitation is required in a regulation in order to assure that the proposed use of an additive will be safe, *(1)* he shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which the additive is intended; and *(2)* he shall not establish a regulation for this proposed use of the additive if he finds that the foregoing data when fairly evaluated do not establish that such use would accomplish its intended physical or other technical effect. In its reports on the amendment before us Congress made this comment on that standard: the phrase 'physical or other technical effect' refers to the objective effect which the additive may have on the appearance, flavor, texture or other aspects of a food. The question whether an additive produces this effect (or how much of it is required for such effect) is a factual one, and does not involve any judgment on the administrator's part of whether this effect results in any added 'value' to the consumer of such food or enhances its marketability from a merchandising viewpoint.

"The third standard is that in determining whether the proposed use of a food additive is safe, under the conditions specified in the regulation, the administrator shall consider among other relevant factors *(1)* the probable consumption of such additive and of any substance formed in or on food because of its use; *(2)* the cumulative effect of such additive in the diet of man or animal, taking into account any chemically or pharmacologically related substance or substances in that diet; and *(3)* safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data. In its reports on the amendment before us Congress made this comment on that standard: in determining the safety of an additive the administrator would have to consider not only the food to which it is directly added, but also other foods derived therefrom. For example, in evaluating the safety of an additive for poultry feed, the administrator would have to consider any residue that might appear in eggs produced by the poultry. Similarly, in determining the safety of an additive for cattle feed, account would have to be taken of any residues in the milk and edible flesh of the animal.

"The fourth standard governs the form of the regulation for a food additive. As a result this regulation may or may not be in accord with that proposed by the petitioner; it may prescribe conditions under which the additive may be safely used, with respect to one or more proposed uses thereof; these conditions include, but are not limited to, specifications as to the particular food or classes of food in or on which the additive may be used, the maximum quantity of it which may be used or permitted to remain in or on such food, the manner in which the additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for the additive which the administrator deems necessary to assure the safety of its use. This standard invites the following comment: a regulation under such law should not differ from that proposed by the petitioner, unless this difference is supported by relevant data before the administrator and it is required to protect the public health. For the industrial safety pretesting law is distinguished from the administrative safety control one, in that it is designed to establish a regulation proposed by the petitioner, if and to the extent it is supported by the relevant data before the administrator.

"We should also note the following general comments on these four standards: they should be duly regarded in the industrial safety pretesting of a food additive; and in the industrial development of a petition for an administrative regulation, which prescribes the conditions under which such additive may be safely used.

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"In conclusion we may say:

"*First.* This analytical discussion of the amendment before us justifies our introductory statement that it is a law of fundamental protective significance to the consuming public and the food and chemical manufacturing industries alike. While this law creates a broad and strong government regulation of these industries in the circumstances, it is a democratic regulation from the standpoint that it has an industrial origin in its major pretesting requirement. And while this expensive requirement is a practically severe one for a smaller food manufacturer, he may be relieved from it on a due guaranty basis. Moreover we should here record that responsible food and chemical manufacturers have long voluntarily practiced the pretesting requirement of this law, to protect the public health.

"*Second.* This amendment manifestly imposes a great responsibility on the chemical profession, to assure due industrial compliance with it; and that responsibility must be fully realized, both to protect the public health and to provide essential technological progress for ever higher food standards of living.

"*Third.* Because the law of this amendment is an historic one which marks the most important advance in our national pure food law in its entire history, The Food Law Institute will immediately publish its legislative record for permanent reference by all concerned. Moreover because this law creates infinite regulatory and scientific problems, The Food Law Institute has arranged to have a conference with the Food and Drug Administration on November 24-25 in Washington, to discuss the immediate problems for their due solution; and representative food and chemical manufacturers will be invited to attend it. We hope that this conference (for example) may produce an FDA manual on the law, which explains its application and administration to the available extent." **[The End]**

The New Food-Additives Law

Participating in the September 11 Symposium Meeting of the American Chemical Society, in Chicago, the Commissioner of Food and Drugs Took a "New Look at the Subject" of Additives Legislation

IT IS INDEED A PLEASURE to join the distinguished speakers on this panel and participate in this symposium on the food-additive laws. It is timely to take a new look at the subject, since the Congress enacted just last month, and the President signed into law, the food-additives amendment of the federal pure food and drug law. This is known technically as Public Law 929 of the Eighty-fifth Congress. First, let's take a brief look at events leading up to its passage.

The original Federal Food and Drugs Act of 1906 did not afford good control of poisons added to food. Poisons could be used unless the government could prove that they might render the food injurious to health. Each food was considered separately. There was no provision for determining the additive effect of the same or different poisons that might be in the separate components of the diet.

The Federal Food, Drug, and Cosmetic Act of 1938 represented a great improvement in this situation. The 1938 law proscribed the addition of any poisonous substance to food except where required in production or unavoidable by good manufacturing practice. When a substance was required or unavoidable, the Secretary of Health, Education, and Welfare could establish by regulation a "tolerance" fixing the maximum quantity that might be present without hazard to the public health.

While this law forbade the addition to food of any substance known to be poisonous or deleterious, it left without adequate control the use of chemicals that had not been tested enough to show whether or not they are poisonous. It did not prevent the addition of untested and inadequately tested chemicals to the food supply, and left to the

By GEORGE P. LARRICK

government the job of determining, while a material was being used, whether it was safe.

This deficiency of the 1938 Act has been studied by Congress for eight years. In 1950 it formed a select committee to investigate the use of chemicals in food. Most of you are well aware of subsequent developments. Two years later, the select committee, commonly referred to as the Delaney Committee because it was under the chairmanship of the distinguished Congressman from New York, James J. Delaney, submitted its report and recommended that a better law be passed to regulate the addition of chemicals to foods. Numerous bills were introduced in later Congresses and finally—in August of this year—the food-additives amendment of 1958 was passed by Congress. It was signed by the President on September 6.

This new law is similar in many respects to a law that was passed in 1954 to achieve a better control of pesticide residues: the pesticide-chemicals amendment of the Food, Drug, and Cosmetic Act.

The substances covered by the Food Additives Amendment are those additives not generally recognized by competent experts as having been adequately shown to be safe under the conditions of their intended use. The amendment covers substances that are added intentionally in foods as well as those that may reasonably be expected to become a component of food incidentally or to affect its characteristics adversely to the safety of the food. Use of ionizing radiation in food processing is covered by the amendment and will need to be established as safe before commercial use.

Substances commonly used in food before January 1, 1958, and generally recognized as safe because of experience based on such use,

are exempt from the law. Thus, a great many ingredients will not have to go through the clearance procedures of the bill.

Substances that get into food accidentally, such as lead ores, for example, are not covered by the legislation. These substances, if proper precautions are taken, would not reasonably be expected to get into food; if they do get in, the food is illegal under the basic 1938 law. We believe we have adequate authority to control such adulterations.

Other additives not covered by the new amendment are pesticide chemicals which, as mentioned earlier, are already taken care of under the pesticide-chemicals amendment and also substances that have already been approved by the government for use in food under the Food, Drug, and Cosmetic Act, the Meat Inspection Act or the Poultry Products Inspection Act.

Requirements of New Amendment

Briefly, the new law makes the following requirements with respect to additives within its jurisdiction:

(1) The person who wants to promote a new food additive will have to test it for safety on animals, and submit the results of the safety tests to the Food and Drug Administration of the United States Department of Health, Education, and Welfare.

(2) Scientists of the Food and Drug Administration will study the safety data and reach an independent decision as to the suitability of the new ingredient for use in our food supply. If the evidence clearly demonstrates that the material is a suitable component of food, then the Department will issue a regulation stating safe permissible uses for the material. But if there is a question as to the safety of the additive, the Department will not permit it and the public health will be safeguarded in a way that has not been possible heretofore.

(3) The Department is not permitted to sanction a use of an additive that promotes deception of consumers. If the additive can only be used in a limited amount, to safeguard health, the Department must allow only the quantity needed to accomplish the intended technical or physical effect, and this amount will be allowed only if it is safe.

(4) In case the government and industry are unable to agree about the contemplated use of food additives, the bill permits appeal procedures that are incorporated in the present law. Industry has a right to a public hearing on the suitability of a proposed additive and the right to appeal an adverse government decision to the circuit court of appeals.

Obligations Imposed

Next let us consider the broad obligations that it places on government and industry:

We are now drafting procedural regulations to explain in detail how the law will be administered. These will be similar in many respects to the regulations issued under the pesticide-chemicals amendment.

We are ready to consult with industry representatives on the status of food additives already in use and on the testing procedures needed to establish the safety of those additives that have not already received the necessary clearance. The testing procedures are well known to pharmacologists throughout the country, for they have been in use for a number of years. Our pharmacologists and chemists have already published papers explaining in some detail the type of testing that is considered necessary. The Food Protection Committee, National Research Council, has issued a pamphlet, *Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Food,* that gives an excellent general discussion of the types of testing needed.

We must be careful in establishing tolerances for additives. Animals do not always respond to chemicals exactly as man does. This fact requires us to allow an appropriate safety factor. Our tests are made on selected strains of healthy animals maintained on good food and under good laboratory conditions. But the population of the United States is not made up of one selected strain; many people are suffering from illness of one kind or another and, hence, are more susceptible to injury. For example, many people have to restrict their salt intake. We found a few years ago that such persons are much more susceptible to harm from lithium than those on a normal diet. Other special diets are common. Some people have to restrict their intake of carbohydrates and others, their intake of fats. As the medical profession learns more about the effect of diet on health, we will see more special diets in general use. All these circumstances must be allowed for in establishing safe conditions for using food additives.

A general guide that scientists have developed for translating animal-test data to a safe tolerance level for man is that one hundredth of the amount of additive that is safe for the animal will be safe for man. While this a just a broad guideline, it does illustrate the care that we must take in translating animal data to probable effects on man.

We must remember, also, that there are situations in which the usual animal test procedures are not sufficient. If the standard chronic

studies left any question about the chemical's tendency to cause cancer when ingested, we would not be permitted to allow it in food until appropriate additional tests show that it does not produce cancer when eaten. If there were reason to suspect that the additive might supplement or enhance a deleterious effect of other chemicals in the diet, then suitable tests would be required to show that the combined effect of all such related chemicals would be without hazard.

While the job of establishing safe tolerances is formidable, it is by no means hopeless. Sound test procedures are available, and they are continually being improved. We will sanction chemicals in food under conditions that are demonstrated to be proper and safe.

The second phase of our work will start when the first petition for a regulation to permit use of a food additive is received. We are prepared to start processing petitions now. We cannot handle a flood of them at the moment, but industry is not apt to submit a flood of petitions in the immediate future. We are going to do our very best to handle petitions and inquiries and other work related to food additives expeditiously, but there is one thing that I should call to your attention: Many additives are going to need clearance under this new law. There is no provision here, as there was in the pesticide amendment, for the charging of fees to defray the cost of administering the law. Therefore, we will have to administer it from appropriated funds. We cannot—except on a very temporary basis—without sacrificing essential public-health services already under-way, take funds appropriated for other purposes and divert them to the processing of food-additives petitions. It is going to take money to do the new job and the type of service that we are able to give is going to depend upon whether we have adequate funds. We have already recommended to the Department that a moderate supplemental request for funds be submitted to the Congress to get the necessary funds, but this cannot be done until the new Congress meets in January of next year.

Now what is industry's job under this new law? The first task, I would say, is for everyone concerned with the law to get thoroughly acquainted with it. If you don't have a copy, you ought to get one. Separate mailing lists are maintained for releases on pesticides and on food additives. If you would like your name added to one or both of these lists, mail your request to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C.

Each firm will need to determine whether each chemical it is using in food now is subject to the amendment and, if it is, will have to

receive a clearance for it. I mentioned earlier that we are available now to discuss such questions with you, either in person or by letter.

Industry will need to develop the data necessary to establish the safety of those additive uses that do come under the amendment and have not already been cleared. The law allows 18 months from the date of its passage for this clearance for additives in use prior to January 1, 1958, and it gives the Secretary of the Department the authority to extend that time as much as an additional 12 months where the extension is necessary and will involve no undue risk to the public health. Eighteen months sounds like a long time, and some may be tempted to do nothing for awhile. That would be a serious mistake. Our experience under the pesticide-chemicals amendment, which provided essentially the same type of transition period, showed the wisdom of prompt action. The firms that started working immediately after the new law was passed in 1954 generally had the status of their pesticides clarified by the time the law became fully effective. One or two firms delayed and did not have facts to warrant the necessary clearance when the time came. They had to stop marketing their products for use on food crops. We urge everyone who needs clearance for a use already being made of a food additive to start immediately in order that he will not get caught at the last minute.

Another thing industry needs to do is not mentioned in the legislation. It is imperative that you tell consumers why additives are used in food and how the consumer benefits. In recent years there has been a growing concern by the housewife over the safety of the food supply. Intelligent people are coming to us more and more with the question: "Is it true what they are saying about our food supply? Is it really as bad as I hear?" It is not enough for you in industry and for us in government to know the consumer benefits that result from use of food additives. We must let the consumer know, too. Let's start telling the consumer the facts about America's food supply: that our country has the best food supply in the world today; that with this new law it has the best safeguards it has been possible to develop; and that the additives that go into food are there to improve the food and to bring it to the housewife in better condition and in a more convenient form. If industry fails to get this story across to the housewife, a very important potential secondary benefit from the new law will be lost.

How do you build up justified public confidence in these additives? Some people think that the best way to deal with a food additive

is to conceal the fact that it is used—keep the consumer from knowing what is present. That is absolutely wrong in our opinion and, if that course is pursued, you assuredly will undermine the consumer's confidence in your products.

The consumer has a right to know what is in her food. That right has been recognized for over 50 years and is firmly established in the state and national food laws in this country and many other nations of the world. The way to build consumer confidence in your products is not to hide the fact that additives are used, but to tell what the additives are, that they are safe, and what good they do.

We would like to suggest a technique that we think would help get the story across: Devise a simple system of naming the chemicals that go into food. For many years the drug industry has been devising short, simple names which are adopted by common consent as the common name by which the drug will be called. For example, the drug "3-chloro-7-methoxy-9-(1-methyl-4-diethyl amino butyl amino) acridine dihydrochloride" is known simply as "quinacrine hydrochloride."

Similarly, short simple names have been adopted for pesticides, to be used in place of long, jaw-breaking chemical designations.

We think the same thing can be done for the names of food chemicals, so that the "common or usual name" required by law can be met by a short, universally agreed-upon synonym for the chemical name. This involves setting up an industry committee on nomenclature or some other mechanism to make sure that the synonym adopted will be known and understood by all concerned, and will receive official recognition. We recommend that you explore the ways in which this has been done with drugs and pesticides. It must be understood, of course, that such "common" names as here contemplated could not be trademarked, but must be available to all. For example, aspirin is the common name for acetyl salicylic acid regardless of the brand.

I thank you for giving me this opportunity of meeting with you to discuss what we regard as one of the most important advances in the food law in the last 20 years. In closing, we invite you to visit our offices if you are in Washington or one of our field districts or to write or telephone us about any problems that develop as this new amendment goes into effect. We will continue our traditional "open-door policy." We will work with you to get this new law operating as smoothly as possible. Cooperation and mutual good will will do the job. **[The End]**

Establishing Tolerances for Food Additives

By WINTON B. RANKIN

The Writer, Assistant to the Commissioner, Food and Drug Administration, United States Department of Health, Education, and Welfare, Spoke at the American Chemical Society Symposium on Viewpoints on Food Additives, Held September 11 in Chicago

THE FOOD ADDITIVES AMENDMENT of 1958 was signed by the President and became law on September 6. Known also as Public Law 929 of the Eighty-fifth Congress, it amends the federal pure food law (the Federal Food, Drug, and Cosmetic Act of 1938) with respect to additives used in food. It corrected two deficiencies in the pure food law:

(1) The 1938 law allowed chemicals to be added to food without any advance testing to establish their safety. Some chemicals were used before any one suspected that they might have ill effects. When this occurred, the scientists of the Federal Food and Drug Administration ordinarily had to make a laboratory investigation to determine whether they were safe. The tests were performed on animals and generally took two years or more. Meanwhile, people were eating food containing the additives and being exposed to their possibly harmful effects.

The new law corrects this by requiring a food additive to be tested for safety, generally by industry, and accepted for the proposed use by the Government before it may be shipped across state lines or used in food subject to the federal law.

(2) The new law permits the use of new additives at safe levels to advance food technology. It removes restrictions formerly present that blocked progress unnecessarily.

Let us analyze the law to determine (1) substances subject to the law, (2) substances not subject to the law, (3) experimental data required to justify approval of a new use of a food additive, (4) how the Department of Health, Education, and Welfare decides whether to approve an additive, (5) appeals available from Department decisions and (6) when the law is effective.

Substances Subject to Law

To be subject to the procedures of the new law, a substance must meet two conditions:

(1) It becomes a component of food or otherwise affects the characteristics of the food, or may reasonably be expected to do so, under the intended conditions of use.

(2) It is not generally recognized among appropriately qualified experts as safe under the intended conditions of use. Both old and new chemical food additives are covered if their use is not known to be safe.

Additionally, food exposed to radiation, such as food treated in an atomic pile or by an X-ray machine, would have to be tested for safety before it is marketed.

Substances Not Subject to Law

Substances Generally Recognized Among Appropriately Qualified Experts as Safe.—These would include additives used according to a sanction or approval given before January 1, 1958, by the Food and Drug Administration under the pure food law or by the Department of Agriculture under the Meat Inspection Act or the Poultry Products Inspection Act.

Pesticide Chemicals, Pesticide Residues on Crops (Raw Agricultural Commodities) and Pesticides Residues in Processed Foods which Result from Legal Uses of Pesticides on Crops.—The named substances are not subject to this law. They are dealt with under another amendment to the pure-food law (the Pesticide Chemicals Amendment of 1954).

Some examples of additives whose use should be cleared under the amendment are ethylene oxide as a fumigant for processed foods; 8-hydroxyquinoline sulfate as an ingredient of cottage cheese coagulator; nitrated flour for use in bakery products; and polyoxyethylene sorbitan esters of fatty acids for various uses in foods.

Some additives that would not have to be cleared are salt, sugar, monosodium glutamate, citric acid, pepper and many other commonly used seasonings, also shortening such as butter, margarine, and lard, and other ingredients too numerous to list here; nordihydroguiaretic acid (NDGA) in fat as an antioxidant (0.1 per cent); and an insecticide on a growing crop to kill insects (but if the same insecticides were intended for application to a processed food, the use would have to be cleared under the new law).

Experimental Data Required to Justify Approval of New Use of Food Additive

The person who wants to promote a food additive should petition the Food and Drug Administration to issue a regulation stating the conditions under which it may be safely used. The petition should contain, among other things: (1) the name and all pertinent information concerning the food additive, including where it is available and its chemical identity and composition; (2) a statement of the conditions of the proposed use of the additive; (3) all relevant data bearing on the physical or other technical effect the additive is intended to produce, and the quantity required to produce such effect; (4) a description of practical methods for determining the quantity of the additive in or on food, and any substance formed in or on food because of its use; and (5) full reports of investigations made with respect to the safety of the additive.

Further, the Secretary of Health, Education, and Welfare may require the petitioner to furnish a full description of the methods used in, and the facilities and controls used for, the production of the additive and to furnish samples of the additive. (Upon occasion, certain additional information may be required as indicated in the law itself.)

How Department Decides Whether to Approve Additive

The Department of Health, Education, and Welfare will publish in the *Federal Register* a notice of the proposal made by the petitioner and, after considering any comments on or objections to the proposal, will issue an order stating conditions under which the additive may be used safely or denying the petition. These actions must be taken within definite time limits.

The law sets forth precise rules to guide the Department in acting on a petition. For example, a regulation may not be issued permitting an additive in food (1) if the data fail to show that the proposed use

will be safe (and the law says that the additive must not be considered safe if it is found to induce cancer when ingested by man or animal) or (2) if the proposed use would promote deception of the consumer or would otherwise result in adulteration or misbranding of food within the meaning of the pure-food law.

Additionally, if it is necessary to restrict the total amount of a chemical that may be used in food to safeguard public health, the Department must not allow the chemical to be used unless it will accomplish the intended physical or other technical effect or allow more of the chemical to be used than is reasonably required to accomplish such effect.

Appeals Available from Department Decisions

Anyone adversely affected by an order with respect to use of a food additive may file objections to the order and ask for a public hearing on the objections.

After the hearing, the Department will issue a new order based on a fair evaluation of the entire record of the hearing. The new order will be subject to judicial review in the United States Circuit Court of Appeals, in the event of actual controversy.

When Law Is Effective

Petitions now may be filed requesting approval of food-additive uses.

Beginning 180 days after the President signed the bill, we will be authorized to take legal actions because of the shipment in interstate commerce of a new additive, or a food containing it, which has not been determined to be safe.

However, if commercial use of the additive began before January 1, 1958, the law allows 18 months for development of the necessary safety data, provided there is no evidence that the additive is unsafe. This 18-month period may be extended by the Secretary for not more than an additional 12 months where necessary and where the extension will not result in undue risk to the public health.

How does this law affect the food industry? It is not going to change current practices materially for the more responsible elements of industry who, for years, have voluntarily tested new substances before adding them to food, and have discussed their findings with us before marketing the additive, or the food containing it. This, basically, is what the new law requires.

Type of Testing Required

Now let us consider some of the scientific aspects of the requirements of this new law. What testing is required to show that an additive is safe and suitable for food use?

The basic procedures for evaluating safety are outlined in the pamphlet *Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods*, prepared by the Food Protection Committee of the National Research Council, and in several papers published by members of our pharmacology and food divisions. To summarize some of the more important points:

Scientists must know what the additive is before they can make a decision about its safety. If it is a single chemical, it should be identifiable in chemical and physical terms. If it is a mixture of chemicals, the components should be described, and a reproducible composition assured by reference to physical and chemical constants. In either event, it is essential that the substance tested on animals for safety be the same substance and of the same degree of purity as the material to be employed commercially in food.

Analytical methods must be available to determine the concentration of the additive in the foods in which it is to be used, and frequently in animal tissues and fluids as well. This should include information regarding the stability of the additive and what is formed when it reacts with components of the foods it will be used with.

The safety of the additive must be determined by feeding it to test animals. Tests begin with feeding of the additive to laboratory animals, such as rats, to determine what amount is required to kill them in a short time. This is the acute-oral-toxicity test.

Next comes a subacute-oral-toxicity test, in which test animals are fed for 90 days at each of several feeding levels to determine what happens. The effects of the chemical on food consumption, growth, mortality rate, blood and urine composition, weight, and microscopic structure of the organs are determined.

Most important is the test for chronic oral toxicity. This is conducted on the premise that the possible effect of the lifetime consumption of a chemical in man's food cannot be predicted from results of tests less stringent than lifetime feeding in a short-lived animal, supplemented by one year or longer of feeding in another species of test animal. Very small amounts of chemical are fed throughout the life span of labora-

tory animals, and the animals are examined at autopsy in a search for hidden damage to internal organs. Various other biochemical and pathological procedures are carried out to discover the fate of the substance in the body—whether it is excreted, unchanged or stored, or broken down into other chemicals.

Additionally, observations are made on such things as growth, food consumption, mortality, and effect of the chemical on the blood stream and on the behavior of the animal. The effects on ration digestibility and utilization and on lactation and reproduction are observed closely. Frequently, it is desirable to study in the test animals the biochemistry and metabolic fate of the additive, as well as its effect upon the nutritional quality of the food.

The chronic-toxicity test also gives information on any tendency of a chemical to induce cancer when consumed for a lifetime. If the results leave a question as to carcinogenicity, more detailed tests would have to be conducted. An additive may not be considered safe if it causes cancer when fed to test animals.

There must be data to permit the scientists to determine the probable intake level of the chemical. Under certain conditions, the Secretary is required to limit the amount of additive which may be used to a level not higher than that reasonably required to produce the intended physical or technical effect, or to refuse to permit the additive at all if the evidence does not show it will produce the intended effect. In such cases there must be evidence showing that the additive will accomplish the desired physical or technical effect, and what quantity is needed to produce the effect. That is something that can be established objectively. If it is desired to put a new substance into food to emulsify it, the evidence must show that the additive will, in fact, have an emulsifying effect on that food. If it is an emulsifying agent, if the quantity proposed for use is safe, and if its use will not promote deception or other violation of the law, then the applicant is entitled to a regulation stating the conditions under which that emulsifier may be used. We do not attempt to determine whether it is economically profitable for industry to use it.

What Safety Factor Is Used

It is a tremendous responsibility to determine the conditions under which a new chemical may be used safely in man's food supply. Our scientists must consider the possibility that the new substance may

supplement or enhance the physiological action of the other chemicals already present in the diet. The animal tests are ordinarily performed on healthy animals maintained under good laboratory conditions. The effect the additive may have when fed to a population consisting in part of people on a poor diet and people suffering from serious diseases must be considered. To take care of this and other problems, the pharamacologists use what they call a "safety factor." They don't allow in man's diet the maximum amount of chemical that fails to cause injury to animals. They allow considerably less. A broad guide that has proved useful follows:

(1) Find the amount of an additive that causes no harm to the test animals.

(2) Assume that the average man is ten times as sensitive to the additive as the test animal.

(3) Assume that some men are ten times as sensitive to the chemical as the average man.

(4) Combine these safety factors and allow in man's diet only 1/100 of the quantity of a chemical that is safe in the animal's diet. This is a guide only and may be varied as scientific data indicate to be proper.

Pharmacological Action v. Chemical Structure

It is important for those of us who are chemists to recognize that pharmacologists may not be able to predict biological effects of chemicals as readily as we can predict chemical reactions. A couple of examples will show why:

Urea is a common element in the body and several grams are excreted every day. In the concentration in which it occurs, it does not cause trouble. Replace the oxygen in the urea with sulfur and you have thiourea, a compound that is quite similar but is a violent poison to the warm-blooded animal. Thiourea poisons the thyroid gland, causes goiter, and produces cancer of the liver in test animals.

A dilute solution of acetic acid or vinegar is a common food ingredient. Replace one of the hydrogens with a chlorine atom and you have monochloracetic acid, a compound quite similar chemically. Pharmacologically, monochloracetic acid is an enzyme poison which interferes seriously with the storage and release of energy derived from food.

Thus, we chemists must not conclude that it is possible to predict the pharmacological effect of a new compound solely on the basis of its chemical formula. There is no easy way to avoid the testing of food additives on animals to establish their safety.

It has indeed been a pleasure to meet with you and discuss the new food-additives law of 1958. The Food and Drug Administration is prepared now to handle petitions for regulations sanctioning new uses of food additives. If you have any questions before asking for approval of a new use or before starting laboratory work to develop data in support of a petition, feel free to write us, telephone us, or come to our offices for an informal discussion. We look forward to working with you as this new law goes into effect. **[The End]**

POSTHARVEST PESTICIDE CHEMICALS ON CANTALOUPES

Retail sales displays of cantaloupes removed from containers must bear counter cards declaring the presence, and the names, of postharvest chemical preservatives. The impracticality of requiring the retail store to name on the counter card all of the postharvest pesticides on citrus fruit prompted the proposal of a regulation requiring that the counter card state only that a preservative has been used, and that the specific preservative need not be named.

This ruling was contained in a recent letter from Commissioner of Food and Drugs George P. Larrick to Hon. Lister Hill, chairman of the United States Senate Committee on Labor and Public Welfare. Commissioner Larrick wrote, in part:

"Cantaloups and other produce of the soil are not required to have a sticker label on them for . . . [the] purpose [of the declaration of the presence, and the names, of chemical preservatives]. If they are treated with a pesticide chemical after harvest to prevent deterioration, it is enough that the shipping container has a label giving this information. If the cantaloups are taken away from the containers for retail sales display, all we require is that there be a counter card containing the information. Each melon need not be marked.

"Pesticide chemicals applied before harvest are used under spray schedules and other safeguards developed by the Department of Agriculture and disseminated by the county agents, and by labeling on the pesticides themselves. Since the packing-shed operator ordinarily has no means of knowing what pesticides may have been used in growing all the fruit he buys, we have issued an exempting regulation recognizing that it is impractical for him to label fruit with information as to the preharvest treatment. We could not extend this exemption to postharvest treatments because we could not make the statutory finding that the label declaration was impractical.

"We have recognized that it may be impractical in the retail store to name on the counter card the pesticides on citrus fruit, and have proposed a regulation to require that the counter card have only the information that a preservative has been used, but not the name of the preservative."

Parts per Million of What?

By DONALD D. STARK

Mr. Stark—an Attorney, of Corona, California—Examines the Problem of Establishing Tolerances for Permissible Pesticide Residues in or on Raw Agricultural Commodities. He Delivered His Paper at the August 26 Meeting of the American Bar Association, at University Park, California

IT IS THE PURPOSE of this paper to re-examine the validity of the use of the "as is" measure of tolerances for permissible residual pesticides under the Miller Amendments to the Federal Food, Drug, and Cosmetic Act. In that connection, it is believed that the current language of the proposed food-additives amendment [1] [since signed into law by President Eisenhower] demonstrates and re-emphasizes the uncertainty resulting from the present "as is" basis of measuring tolerances.

The object of the pending food-additives amendment is essentially the same, as applied to intentional food additives, as that which lead to adoption of the Miller Amendments relating to residual pesticides.[2] In both instances, procedures are provided for pretesting of pesticides or intentional food additives and the establishment, thereby, of tolerances which will protect the health of consumers and still allow advances in food production and food technology by permitting the use of such pesticides and intentional food additives at safe levels.

There has been little, if any, significant frontal opposition to the basic purpose and thrust of the proposed food-additives amendment. Perhaps this merely reflects everyone's position as being against sin.

[1] H. R. 13254, 85th Cong., 2d Sess.

[2] Both amendatory bills grew out of the 1952 hearings on the Food, Drug, and Cosmetic Act. (See H. Rept. 2284, 85th Cong., 2d Sess., p. 2.)

The major area of dispute and of legislative compromise has been in the field of administrative procedure and techniques to carry out the admittedly sound objective. H. R. 13254, as reported out of the House Subcommittee on Health and Science, appeared to have met the majority of the industry objections to the Administration bill.[3] Even with the deletion from H. R. 13254 made by the full House Committee on Interstate and Foreign Commerce,[4] the procedures appear satisfactory. This paper is concerned with a somewhat less-generally recognized problem of administrative procedure which is common to the Miller Amendments and the proposed food-additive amendment.

The Miller Amendment provides for "a tolerance" to be established for pesticide chemicals in or on raw agricultural commodities.[5] No method of expressing that tolerance is prescribed in the statute. The Food and Drug Administration adopted an "as is" method, whereby the allowable tolerance for a given pesticide is expressed in terms of parts per million of the pesticide chemical on the raw agricultural commodity in its natural form.

An unsuccessful attempt was made by researchers in the citrus industry to point out the uncertainties of the "as is" measure of tolerance and to propose the use of a nonaqueous or dry-matter basis.[6] The failure of FDA to adopt the more definite and logical nonaqueous-matter basis has now resulted in a further complication of statutory language and administrative practice. This problem arose when the legislative draftsmen attempted to co-ordinate operations under the Miller Amendment and the proposed food-additives amendment with regard to incidental additives in the nature of residual pesticides which cannot be eliminated by good manufacturing practice in the processing of food products from raw agricultural commodities.

Before discussing the problems of statutory language which have resulted, it is necessary to review briefly the technical problem in-

[3] H. R. 6747, the Administration bill, was one of eight bills on the same subject before the Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce when it commenced hearings on July 15, 1957. Strong industry opposition to certain procedural aspects of the bill were presented during the extended hearings which followed, and the result was the introduction of H. R. 13254 by Chairman Williams.

[4] On July 28, 1958, the full committee unanimously reported H. R. 13254, after amending it to delete provisions for an optional review by an *ad hoc* scientific advisory committee of an order against an additive.

[5] Section 408(a)(1), Federal Food, Drug, and Cosmetic Act, 21 USCA Sec. 346(a)(1).

[6] W. E. Baier and C. W. Wilson, "Proposed Basis for Tolerances of Insecticide Residues in Food Products," 9 *Food Drug Cosmetic Law Journal* 170 (March, 1954).

volved in establishing tolerances for either residual pesticides or intentional food additives.

Problems of Establishing Tolerances

What is it that a tolerance for either residual pesticides or intentional food additives is intended to express? Broadly stated, the purpose of establishing tolerances is to assure safety of food for consumption:

> The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. . . . The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the accumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.[7]

At the risk of oversimplification, the problem of establishing tolerances can be described as follows: First, it is necessary to establish the toxicity of a given chemical by both acute and chronic tests on animals: "Toxicity is relatively absolute for any chemical compound and for any animal and for a specific route of administration." [8] Having established the toxicity of the chemical for selected animals, it is then possible to calculate what is referred to as the "safe level" of the same chemical for man.[9]

The toxicity test, therefore, can be characterized as a relatively precise determination of the safe level to which any chemical can be ingested by man. The difficulty in establishing a tolerance arises in the next step, wherein the safe level of the chemical itself must be converted to parts per million of the residual pesticide or intentional food additive in the food to be consumed. It is at this point that the question can and should logically be asked: "Parts per million of what?"

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[7] H. Rept. 2284, 85th Cong., 2d Sess., pp. 4-5.

[8] Testimony of Dr. Maurice H. Seevers at p. 337 of *Hearings Before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 85th Congress, on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food* (hereinafter referred to as *"Food Additives Hearings"*).

[9] "For every compound there is a level of intake below which there is no discernible effect upon health. In toxicologic testing, a level of intake of a compound having no demonstrable effect upon at least two species of animals when fed over a long period is generally referred to as a 'no-effect level'. Extrapolation from the 'no-effect level' in animals has been successful in defining a level of intake which has a negligible probability of injuring any individual in the population. This level is commonly referred to as the 'safe level' for use by man." (Bernard L. Oser, "Insignificant Levels of Chemical Additives in Food," 13 *Food Drug Cosmetic Law Journal* 477, 478 (July, 1958).

The toxicity test was made with the undiluted chemical, yet:

> . . . one of the cardinal principles of toxicology is that every substance has a "no effect" dose and every substance also has a toxic dose. . . . In other words, we can take any compound and dilute it out to a concentration where it may be ingested without any harm whatsoever . . . we are talking in strictly quantitative terms; and safety is a quantitative term always, and it will never be anything else.[10]

Here the element of uncertainty and judgment enters the establishment of tolerances:

> Any decision to use an intentional additive must be based on the considered judgment of properly qualified scientists that the intake of the additive will be substantially below any level which could be harmful to consumers. The decision as to a safe level should be based on knowledge of the maximum dietary level that produces no unfavorable response in test animals, of the severity and type of response in animals above that level, and of the estimated potential intake of the additive.[11]

It thus becomes necessary to estimate dietary habits of consumers of the foods to which the chemical under consideration is to be applied. Theoretically, when it has been determined how great a volume of the food in question is likely to be consumed—all safety factors being considered—by measuring the bulk to be consumed and knowing the bulk of the pesticide chemical or food additive which constitutes the safe level for human consumption, a simple formula or tolerance can be expressed in parts per million. The crux of the matter lies in the estimate of dietary consumption.

Nonaqueous-Matter Argument

The Food and Drug Administration has predicated its tolerances under the Miller Amendment on an "as is" basis. It has been forcefully suggested that this injects considerable uncertainty in the administration of the tolerance, due to the varying water contents of even the same food or products.[12]

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[10] Testimony of Dr. Maurice H. Seevers, at pp. 338-339 of *Food Additives Hearings*.

[11] *General Principles Governing the Use of Food Additives* (Report of the Joint FAO/WHO Expert Committee on Food Additives, First Session, Rome, Italy, December 3-10, 1956, copied at p. 321 of *Food Additives Hearings*).

[12] "Certain insecticide residues are quite soluble in the essential oils—for example, in oil of orange. If the . . . ["as is"] tolerance were greatly exceeded in the oil, all that would be necessary to make a marketable product well under the tolerance would be to cut the oil to derive a household extract or a flavoring emulsion. Only a few drops . . . of the oil will suffice to flavor a food composition where a teaspoon of the extract might be required; this ease of measurement and better dispersion of the extract over the oil are the advantages of the extract form of flavor to the housewife but perhaps not so desirable to the larger user. The final result as to insecticide residue entering the finished food composition is the same, so why should one of these procedures be held legal and the other not?

"The cutting of vinegar to make a product of lower acid strength might be considered as another example. The dilution of a fruit juice to make an ade or the dilution of concentrated juices to make either natural-strength juice or ades may

The major premise of the argument for using the nonaqueous-matter basis of establishing tolerances is:

> As necessary as water is to the maintenance of life, no animals—not even aquatic ones—can decrease their necessary food intake to an extreme merely by filling up with water. Conversely, if all foods which are consumed were completely dehydrated, a person could not eat as much weight of these dehydrated foods as he does of the same foods in the fresh state. The reason is that the food value largely is contained in the dry matter and, in the long run, just so much dry matter and no more or no less is required in the diet.[13]

If dry matter, is, in the long run, the measure of dietary consumption and if toxicity tests on the chemicals involved are on a dry-matter basis, it seems reasonable and logical that tolerances should be expressed on an exclusively nonaqueous or dry-matter basis. The significant difference between the nonaqueous and the "as is" basis for establishing tolerances is indicated in the following table:[14]

HYPOTHETICAL CASE OF A TOLERANCE FOR AN INSECTICIDE RESIDUE

Citrus Food	*Nonaqueous Matter Basis, ppm*	*"As Is" Basis ppm*
Single-strength citrus juice	50.0	6.2
Oil-free 65° Brix concentrate (regular process)	50.0	32.3
Essential oil	50.0	50.0
Dried meal	50.0	44.1
Seed oil	50.0	50.0
"As is" dry pectin	50.0	46.3
5.5-grade liquid pectin	50.0	1.5
Fresh grated peel	50.0	12.5
Vinegar	50.0	3.0
Wine	50.0	4.0

As will be noted, assuming a result of 50 ppm, based on a nonaqueous-matter method, the parts per million on an "as is" basis varied from 1.5 ppm to 50 ppm.

In establishing tolerances we are dealing with an expression of the degree of dilution of the pesticide or additive in the food product. The degree of dilution has significance only insofar as it relates to

(Footnote 12 continued)
be still others. All these dilution operations have their very definite place in the distribution to consumers of very desirable and convenient forms of foods and beverages but it seems very unwise that such a dilution operation should permit the production of a food satisfactory for interstate commerce from one which was not. It would seem that either both forms are satisfactory or both should be condemned, depending only upon whether the insecticide residue contributed to the finished food is satisfactorily low." (Baier and Wilson, work cited at footnote 6, at pp. 174-175.)

[13] Baier and Wilson, work cited at footnote 6, at p. 172.

[14] Derived from a table set forth at pp. 174-175 of Baier and Wilson, work cited at footnote 6.

total consumption. It is submitted that since total dietary requirements and, therefore, long-term levels of consumption are controlled by the nonaqueous or dry-matter content of foods, the only consistent and safe method of expressing tolerances is by relating the residual pesticide or intentional food additive to the dry-matter content of the food product in terms of parts per million. To express the tolerance with reference to parts per million of water content of the food is to risk ultimate dosage of the additive in excess of levels deemed proper or to penalize some products, such as concentrates, which are made from raw agricultural commodities complying with the law. The expression of tolerances on a nonaqueous-matter basis, on the other hand, affords an unequivocal method for the enforcement agency and the producer to measure tolerances in both the raw agricultural commodity and in its products.

Current Food-Additives Legislation

When the Administration bill (H. R. 6747) for pretesting of intentional food additives was introduced, it failed to make any provision for products produced from raw agricultural commodities where, as a result of good manufacturing practice, the presence of incidental residual pesticides are reduced in the finished product to a point within the "as is" tolerances prescribed for the raw agricultural commodity. In the hearing record it was suggested that, in defining the term "new additive," it be provided that it should not include:

> . . . a pesticide chemical present in a processed food as the result, through good manufacturing practice, of being derived from a raw agricultural commodity which complies with Section 408 of this act provided that its established tolerance when calculated to the basis of the non-aqueous matter content of the raw agricultural commodity is not exceeded in the processed food when similarly calculated.[15]

Apparently in answer to this criticism, when H. R. 13254 was introduced, it provided an exception in Section 402:

> . . . where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under Section 408, and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of Sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food *when ready to eat* is not greater than the tolerance prescribed for the raw agricultural commodity. [Italics supplied.]

[15] *Food Additives Hearings*, p. 531.

The effect of this amended language would appear to be to avoid the very expensive reconsideration of subtolerance levels of approved pesticide chemicals in raw agricultural commodities when those commodities are used in processed foods. However, the existence of "as is" tolerances for residual pesticides on raw agricultural commodities has apparently forced the use of rather complex statutory language, and the consequent introduction of a wholly unnecessary area of ambiguity, dispute and difficulty of administration, to wit: When is a food "ready to eat"?

A dried prune would be ready to eat after it was soaked and cooked—unless the packager notes on his label that the prunes are ready to eat as packaged. But here one might question whether the FDA would require labeling of dried prunes exceeding the tolerance for fresh prunes that they "must be soaked and cooked before eating." What of jam or marmalade? Certainly, marmalade is not "ready to eat" when taken from the jar. It is ordinarily consumed when spread on bread or toast. It is the total weight of the marmalade *and* toast to be the denominator in the tolerance ratio?

We thus have the original question—"Parts per million of what?" —re-emphasized by the uncertainties of determining what constitutes the denominator of the parts-per-million ratio for tolerance in a food product "ready to eat."

It is submitted that were it not for relating the tolerance in the processed food to an "as is" tolerance on the raw agricultural commodity, the uncertainty of determining when a food is "ready to eat" could be eliminated. Were the FDA to adopt the nonacqueous or dry-matter basis for determining tolerances of residual pesticides, it would then be a simple matter to relate the acceptable tolerance in the finished product by simply providing that:

. . . its established tolerance when calculated to the basis of the non-aqueous matter content of the raw agricultural commodity is not exceeded in the processed food when similarly calculated. **[The End]**

GUIDES AGAINST DECEPTIVE PRICING ISSUED BY FTC

Guides against deceptive pricing were adopted by the Federal Trade Commission on October 2, 1958. Nine major types of fictitious pricing practices are declared unlawful in the guides, issued to the Commission's staff.

The Commission has served notice on all advertisers and sellers that intensified enforcement under the guides has been ordered.

Science and the Food and Drug Administration

THROUGHOUT EACH YEAR, I look forward to the forthcoming meeting of this section because of the opportunity it affords of renewing acquaintance with its members and of being brought up to date on developments in the food, drug and cosmetic field.

As you all know, the scope of the operations of the Food and Drug Administration is enormous. It not only administers the basic Food, Drug, and Cosmetic Act, but it also administers a great number of related acts and is involved in numerous matters with other departments and with the food, drug and comestic regulatory machinery of the various states.

Science is the keynote of the present. Some of the important activities of the FDA which have not received much discussion at these meetings are its important scientific activities.

The Citizens Advisory Committee on the Food and Drug Administration recommended a number of changes in the management and operations of the FDA. These recommendations led to an internal reorganization in the FDA whereby its activities were grouped into five bureaus, with the Office of the Commissioner maintaining direct supervision over administrative management, relations with states, trade, industry and consumer groups, and matters relating to new laws and regulations. The scientific divisions were grouped into the Bureau of Biological and Physical Sciences. The other bureaus are the Bureau of Enforcement, the Bureau of Field Administration, the Bureau of Medicine, and the Bureau of Program Planning and Appraisal.

The Bureau of Biological and Physical Sciences consists of the seven laboratory divisions responsible for the development of the scientific bases of the regulatory and certification programs of the FDA, as follows:

By EDWIN L. HARDING

The Vice President and General Counsel of Kellogg Company, Battle Creek, Michigan, Addressed the Recent Annual Meeting of ABA, at University Park, California

(1) Division of Antibiotics.—The Division of Antibiotics is responsible for operating the certification program on antibiotics. In addition, it maintains a continuing research program to establish specifications for new preparations and new dosage forms, to develop methods of assay, and to check on efficacy and safety of antibiotics.

(2) Division of Pharmacology.—The most important function of the Division of Pharmacology is to evaluate the safety of drugs. It is also collaborating in the cancer-chemotherapy program in conducting the toxicity evaluation of promising anticancer drugs.

(3) Division of Food.—Among other things, the Division of Food is conducting studies on the chemistry of food additives and pesticide chemicals.

(4) Division of Cosmetics.—The Division of Cosmetics deals with the very complex problems in chemistry involving the analysis of coal-tar colors and cosmetics.

(5) Division of Pharmaceutical Chemistry.— The development of chemical and physical methods for the evaluation of drugs for identity and purity is the main concern of the Division of Pharmaceutical Chemistry.

(6) Division of Microbiology.—The lack of simple and practical methods for the detection of staphylococcal food poisoning has seriously hampered efforts to control the same; the Division of Microbiology is conducting research to develop such methods.

(7) Division of Nutrition.—Methods of assay and the development of scientific facts to enable control of nutritional claims is the main concern of the Division of Nutrition.

The necessity for strengthening the FDA's scientific activities was stated in its 1957 annual report as follows:

> Evaluation of the safety of foods, drugs and cosmetics offered to the public in this constantly changing period and the development and improvement of testing methods form the solid foundation of enlightened enforcement activities.

The 1957 report of the FDA stated, regarding one of its outstanding scientific investigations:

> A major survey planned and reviewed by FDA scientists and carried on through inspection personnel throughout the country was concerned with the incidence of severe reactions to antibiotics from 1953 to early in 1957. It covered more than one third of the beds available in the general hospitals of this country and the observations of more than 1,600 physicians. The survey indicated that the great bulk of reported life-threatening reactions to antibiotics followed penicillin injection, and that severe reactions to this drug have increased in frequency as more people have been treated with it.

This survey has been of untold benefit to humanity, and has undoubtedly saved many lives. Some of the other scientific surveys listed in such report are as follows: (1) evaluation of the contamination of foodstuffs by radioactivity resulting from the increasing applications of atomic energy, (2) developing and adopting analytical methods to determine trace levels of toxic chemicals used or proposed for use in food production and processing and (3) a veterinary study involving implantation or injection of 1,500 chickens with diethylstilbestrol preparations.

These are only a few of the many activities of the scientific division.

In making the investigations, the FDA has done much pioneering. It has had to work out new methods, new procedures, and new machines and instruments. It is indeed heartening to know that the FDA was deeply interested in science long before *Sputnik*!

We are greatly indebted to the FDA for its many scientific contributions. It is a privilege to be able to call attention to some of its important behind-the-scenes activities at this meeting. **[The End]**

More State Control in Food and Drug Laws

By THOMAS W. CHRISTOPHER

At the 1958 ABA Meeting at University Park, California, the Author Suggested a Plan Whereby, by Agreement Between the Federal Government and the States, More Food-Drug-Matters Control Would Be Shifted to the States

THE PRIMARY PURPOSE of the food and drug laws, both state and national, is to insure protection of the consumer. There are other purposes, such as fair trade practices, but consumer protection is the very heart of these laws. I should like to make two proposals which would, I believe, increase consumer protection. Both are concerned with state and local enforcement.

The first is that we seek more adequate laws and enforcement on the state and local levels.

With some notable exceptions, such as where milk and drinking water are concerned, the most effective protection given the consumer in food and drug matters comes from the federal government rather than from states or municipalities. Even in states which have effective enforcement machinery, nation-wide distribution makes it difficult at times for a state to provide adequate consumer protection, so it is generally agreed that Washington should take an active and strong interest in this field. In my judgment, it would be a disaster to abandon food and drug regulation to local authorities.

This does not mean, however, that states cannot play an important role in seeing that the American home is provided with the very best foods and drugs.

In the first place, the states, under the police power, have adequate authority. As long as the legislation is based on health needs—and even in many states where it is based on economic considerations, the

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states have the power to act. A state health act cannot interfere with a federal act and a state law cannot discriminate against interstate commerce but, subject to these two restrictions, a state may regulate interstate as well as intrastate goods. For example, there is no reason why a state or a city may not see to it that its milk, from whatever source, is wholesome. It is the lack of exerting the authority now in existence which causes state enforcement to be inadequate.

Two things are needed: In some states, more modern and complete statutes are necessary. In many—perhaps most—states, more money for, and less politics in, enforcement is a requisite.

To get more money for enforcement, to get politics out, and to secure proper statutes where needed is a project worthy of national attention and national energy. There should be a well-organized, nation-wide movement, backed by the reputable food and drug producers, working toward this end.

This is a project in which the press could play an important role. Speaking generally, the newspapers of the United States have been remiss in meeting their obligation in the field of food and drug protection for the consumer. For example, they gave almost no support to the enactment of the 1906 and 1938 federal food and drug Acts.

The second proposal is that machinery be created for enabling the states to do more of the policing and, thus, to transfer some of the federal duties to the states. There are doubtless some areas in which the national government acts simply because the states won't or because the required uniformity in regulation can only be obtained by federal action. The regulation by Congress of intrastate oleomargarine appears to be an example.

If the states would do their duty and if the consumer could trust them, there would be less need for control from the national capital—at least in some areas. But how can we persuade the states to do their duty?

One approach is for Congress to sponsor an organization for this purpose. It would be a kind of "quasi-arbitration conference." It would be made up of representatives of the national government and of the states. As an illustration, each state would have a representative, perhaps appointed by the governor; the federal government would have several representatives, perhaps appointed by the Secretary of Health, Education, and Welfare. This group would elect an executive committee of, say, four state and four federal members. This subcommittee, with a small professional staff, could attend to the business, investigate, and make recommendations to the entire group.

On the recommendations adopted by the conference, Congress would get out of or stay out of designated areas. The conference would secure the cooperation of the states and would act both as a clearing house and as a policing agency.

We would thus have an intermediary group, with official sanction of the states and of Congress, to work with Congress and with the states. By such an arrangement, the states, where they were willing, could assume control in special areas, yet the consumer would be assured of protection.

The details, of course, could fill many pages, and are variable. But the central idea is to create such a conference for the purpose of giving the states more responsibility in the food and drug areas.

For some years, perhaps many, only minor areas would be dealt with. But only the future could tell what eventually would spring from such an arrangement. If the experiment were successful in the food and drug field, the experience would be invaluable for like experiments in other areas of government.

The spending power, with its enormous capacity for accomplishment, could aid materially in insuring the success of the plan. But there are other aids also. The appeal of "home rule" is one. The effectiveness of investigations as a regulatory device is another. The skillful use of publicity and the public forum is a third.

Both of these proposals will require dedicated support. But the public service involved justifies the cost in time and effort which will be required. **[The End]**

CHRISTOPHER

COMMENTS

Thomas W. Christopher is visiting professor at the University of California Law School, at Berkeley.

Agreement to Hold Blameless.[1]—A plaintiff sued a defendant for injury to his mink resulting from mink feed bought from the defendant. At the time of the purchase, and for consideration, the plaintiff agreed with the defendant that the latter made no warranty concerning the fitness of the product for mink feed and that the plaintiff would use it at his own risk and would hold the defendant harmless from tort or contract liability which might arise by reason of the use of the feed.

A statute said that a seller of an adulterated feed is guilty of a misdemeanor. Intent and knowledge are not required. The courts of the state hold that a violation of the statute is negligence per se in a civil suit for damages.

The defendant raised the defense that the plaintiff is a director of the defendant corporation, and so is estopped. The court held that the fact that the plaintiff is a director is not enough to estop him but if, in fact, the plaintiff were guility of contributory negligence growing out of his participation in the defendant firm, then he would be estopped. The court did not say so, but I would suppose that he would be estopped if he were a responsible officer in the corporation even though he had no actual knowledge.

The defendant raised a second objection—that the plaintiff had agreed, for a consideration, not to hold defendant liable. The court rejected this defense on the ground of public policy. In effect, it held that if the statute says an act is negligent, one may not contract away the right to sue for such negligence.

The trial court had held that contracts relieving of liability in employer-employee relationships, safe-place statutes, and public utilities

[1] *Metz v. Medford Fur Foods, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 22,545, 90 N. W. (2d) 106 (Wis., 1958).

were void as against public policy. But it had expressed the thought that the seller of mink feed is not in a business wherein there is a duty of public service. The state supreme court disagreed, writing:

> When the legislature forbade the sale of adulterated feed, declared the performance of the forbidden act to be a criminal offense and imposed a penalty, the public interest in the subject is manifest and public policy declared.

Courts often uphold contracts expressly relieving a party of liability—unless there is some public policy involved. If one party is at a disadvantage in bargaining power, however, the courts may protect him. Thus, a contract which exempts an employer of liability for negligence violates public policy. The same is true as to a public utility in performing the public service. A bona-fide effort to fix liquidated damages in advance often is upheld.

If no public duty is involved, courts generaly uphold a contract relieving of liability, at least where the injured party was fully aware of the terms. In some cases, the courts uphold the agreement even where the defendant's negligence arises from the violation of a statute But there are some statutes where the courts will not uphold such an agreement—employee safety statutes and child labor acts being examples. The present case adds violation of adulterated-food statutes.[2]

Injunction by State Court.—The Minnesota Pharmacy Act imposes criminal penalties for the sale of drugs without a license. The act does not provide for injunctions. However, the state supreme court ruled in a recent decision[3] that equity has jurisdiction to enjoin sales by large grocery chains in violation of this statute.

The court states that there are two basic questions: (1) Does the misdemeanor provision fail to provide the state with an adequate remedy at law? (2) Do the acts of the chains constitute a danger to public health?

The court then writes that the nuisance aspect may be considered, as well as the social consequences, and it points out that an alleged widespread violation of a misdemeanor statute enacted to protect public health is involved. In the face of widespread resistance, the court holds, individual prosecutions may not be an adequate remedy at law.

I would not think that the fact that there was widespread resistance to the statute would alone be enough to give equity jurisdiction,

[2] See Prosser, *Handbook of the Law of Torts* (2d Ed., 1955), p. 303.

[3] *State v. Red Owl Stores, Inc.*, (Minn., 1958).

for otherwise courts could enjoin individuals from committing crimes whenever the crime was a popular one. It is, I suppose, the additional factor of public health that enables equity to move in. Also, this is not an injunction against the world but against named defendants.

• MEDICINAL PREPARATIONS—MISREPRESENTATION •

Laxative . . . A pharmaceutical distributor is charged with making false television advertising claims for a laxative. By these and by other means, the laxative has been represented to rejuvenate inactive, lazy intestinal muscles.

Alleging that the concern's television advertising misleads the public, a Federal Trade Commission complaint cites this typical TV commercial: An animated chart of the human form pictures the muscles as being limp and inactive, as the announcer says: "You see, when the muscles of the lower digestive tract become lazy . . . inactive—you pay the penalty of irregularity." A fine mist falls over the entire screen, changing it to a brighter shade, and the phrase "VITAMIN B-1" is superimposed. Symbolic lines straighten gradually and begin to undulate, while the viewer is told: "But the Vitamin B-1 in . . . puts strength back into these lazy muscles—helps them function by themselves. And doctors say *that* means the return of normal regularity."

Neither the laxative itself nor the vitamin B_1 or any other ingredients will put strength back into inactive, lazy intestinal muscles of the digestive tract or give them new life, the complaint charges. It adds that vitamin B_1 does not fortify or strengthen such laxative effect as the product may have.

Despite other claims, the complaint continues, the product is not an effective treatment for constipation and will not cure the condition or correct its underlying causes or restore regularity.

The advertising describes the product as a "glistening new powder [which] brings different, new kind of relief! Its exclusive ingredient . . . helps clean out poison matter that often accumulates in a constipated system." All of these claims are false, the complaint says; the preparation is merely another of the well-known class of bulk laxatives, and (1) it does not bring a new and different kind of relief, (2) it will not clean out the intestinal tract and (3) an accumulation of poisonous matter does not accompany constipation.

The final charge is that the preparation is not a tonic laxative, and it will not build or put tone into intestinal muscles as represented. (Released September 22, 1958.)

Vitamin-and-mineral preparation . . . A firm is prohibited from falsely representing the curative properties of a vitamin-and-mineral preparation. The Commission has approved a consent order requiring the firm to stop falsely claiming that the preparation is a safeguard against arthritis, diabetes, gastrointestinal disorders, high blood pressure, pernicious anemia, or heart trouble. (Released September 22, 1958.)—CCH TRADE REGULATION REPORTS ¶ 27,454; 27,450.

The Scientists' Forum

By BERNARD L. OSER

Director, Food and Drug Research Laboratories, Inc.

Report on International Symposium at Paris, France

The fourth symposium on foreign substances in foods under the joint sponsorship of the *Commission Internationale des Industries Agricoles* and the *Bureau International Permanent de Chimie Analytique* was held in Paris July 14-19, 1958. Twenty-four countries and 12 international organizations were represented at this conference. Among those present from the United States were Mr. Charles Wesley Dunn, representing The Food Law Institute; Dr. Paul E. Johnson, executive secretary of the Food Protection Committee of the National Research Council; Dr. Wilbur H. Miller, of American Cyanamid Company; Mr. Vincent Kleinfeld, of Washington, D. C., and Dr. Bernard L. Oser, of New York. Technical papers, reports of various subcommittees, and the ensuing discussions were presented, with simultaneous translation into English, French and German.

Among the topics discussed were chemical preservatives; pesticides; antioxidants and their synergists; flavoring agents; antibiotics; physical, chemical and microbiological methods of analysis; phytopharmaceuticals; and legislative and regulatory matters. On the latter subject, a comprehensive report was presented by Mr. Dunn on the legal status of food additives in the United States, with particular reference to the then-pending legislation. His report including annexed tables was made available in printed form at the time of presentation and has been reprinted in the July, 1958 issue of this JOURNAL. It evoked extended discussion and helped to clarify certain misconceptions concerning practices in the United States, particularly the notion that "25,000 chemical additives" are in current use.

Of the reports of the various subcommittees, the one on antibiotics in foods aroused the most active discussion. The report of the chairman, Mr. Alfred L. Bacharach of England, covered comprehensively

the present and possible future applications of antibiotics in food processing and, except for the reservation of one member on a single point, received unanimous endorsement of the subcommittee.

It was the impression of the English-speaking members of the symposium that this conference was more successful than those held previously (in Vienna, Amsterdam and Como) not only because there appeared to be better understanding of the issues involved, but because of the superior facilities for communication. That the proper functional role of intentional additives and the problems involved in regulating their presence and use in foods is more clearly appreciated with each succeeding international conference was manifested by the reactions expressed not only on the floor of the conference, but also in many private discussions. It is expected that the papers and proceedings of the meeting will be published as have those of the previous symposia in this series.

HAIR-AND-SCALP TREATMENT—MISREPRESENTATION

Two firms would be prohibited from falsely claiming that their products can prevent baldness and grow hair, under the terms of a Federal Trade Commission initial order to cease and desist. A Commission hearing examiner issued the order. It is not a final decision of the Commission, and it may be appealed, stayed, or docketed for review.

The examiner ruled to be false the firms' unlimited advertising claims that their hair and scalp preparations will check thinning of hair, prevent and overcome baldness, induce new hair to grow, and cause the hair to become thicker. He pointed out that "three highly qualified and experienced physicians" had testified that the great majority of cases of baldness and thinning hair are of the male-pattern type, for which there is no known cure or effective treatment (except possibly hormone injection and castration). Observing that this testimony was corroborated by the companies' own physician witnesses, the examiner held that the preparations "are wholly incapable of" achieving the claimed benefits in cases of this type.

He ordered the concerns to limit future claims to cases other than the male-pattern type and to stop claiming that their agents or employees are trichologists or have had competent training in dermatology. Joined in the order is the agency which prepared the deceptive advertising.

The FTC's complaint of July 17, 1956, alleged that the advertising was further misleading in that it did not reveal the frequency of male-pattern baldness and the ineffectiveness of the preparations in such cases. Rejecting the proposal of counsel supporting the complaint that these facts be disclosed affirmatively in future advertising, the examiner said that his order reasonably protects the public. He added: "To go beyond that and require that the advertisements contain statistical or other general information regarding male-pattern baldness and the ineffectiveness of respondents' preparations in such cases would seem to be unwarranted." (Released September 22, 1958.)—CCH TRADE REGULATION REPORTS ¶ 27,443.

Foreign Law Comment

By JULIUS G. ZIMMERMAN

Current Developments in Western Hemisphere

Several important developments in the field of food, drug and cosmetic law took place in Latin America in recent months, exemplifying the trends toward modernization, codification and uniformity in this important branch of the law.

On April 15, 1958, a new federal regulation on food additives came into effect in Mexico—the first detailed piece of legislation on this subject matter in the Western Hemisphere and, to the best of my knowledge, in the world.[1] It is interesting to compare it with the recent food-additives amendment of the Federal Food, Drug, and Cosmetic Act in the United States (H. R. 13254) which became law on September 6, 1958.[2]

The legislative techniques and the entire approach to the problem of regulating the conduct of business are very different in Latin America and in the United States, but the primary objectives are very much the same: protection of public health and assurance of good manufacturing and trading practices.

Uniform Latin-American Food Code

The preliminary draft of a uniform Latin-American food code is almost completed.[3] The drafting committee in Buenos Aires (chair-

[1] See "Foreign Law Comment" in the March, 1958 issue of this *Journal*, at pp. 207-208. The complete text of the regulation, in English translation, was published in the June, 1958 issue of this *Journal*, at pp. 353-379.

[2] A detailed analysis of the basic features of the United States food-additives amendment, by Charles Wesley Dunn, can be found in the July, 1958 issue of this *Journal*, at pp. 407-468.

[3] For background information, see the previous articles by this writer: "The Food, Drug and Cosmetic Law of Latin America," 9 *Food Drug Cosmetic Law Journal* 655, 661-662 (November, 1954); "International Aspects of Food and Drug Legislation," 12 *Food Drug Cosmetic Law Journal* 402, 425-426 (July, 1957); and "Legal Research Problems in Latin-American Food and Drug Law," 12 *Food Drug Cosmetic Law Journal* 683, 685-686.

man, Carlos A. Grau) [4] has released the complete text, consisting of 19 chapters, for review and comment. Copies of the Spanish text were made available to the United States Department of Commerce in Washington (American Republics Division, Bureau of Foreign Commerce) which, in turn, is sharing the material with The Food Law Institute and the Inter-American Bar Association Food, Drug and Cosmetic Law Section for the purpose of a common undertaking—an English translation of the individual chapters, copies of which are distributed free of charge to all interested parties by the Department of Commerce and The Food Law Institute.

A list of the chapters follows: Chapter I, "General Provisions"; Chapter II, "General Requirements for the Manufacture and Sale of Food Products"; Chapter III, "Storage, Conservation and Treatment of Foodstuffs"; Chapter IV, "Utensils, Receptacles, Containers, Packaging, Apparatus and Accessories"; Chapter V, "Labeling"; Chapter VI, "Meat and Meat Products"; Chapter VII, "Fats"; Chapter VIII, "Dairy Products"; Chapter IX, "Cereals, Flour and Derivative Products"; Chapter X, "Sugar and Sweets"; Chapter XI, "Vegetable Products"; Chapter XII, "Soft Drinks and Refreshing Foodstuffs"; Chapter XIII, "Fermented Beverages"; Chapter XIV, "Distilled Beverages"; Chapter XV, "Stimulating Products (Cocoa, Coffee, Tea, Maté, Tobacco)"; Chapter XVI, "Food Additives"; Chapter XVII, "Various Products (Animal Food, etc.)"; Chapter XVIII, "Dietetic Products"; and Chapter XIX, "Articles of Domestic Use (Cosmetics, Disinfectants, Insecticides, Soap and Detergents, Toys, Industrial Products, etc.)."

As of October 1, 1958, English translations of Chapters I through VIII and XII were completed and the release of Chapters IX, XIII and XIV is scheduled for the end of October. The very difficult technical translation work is done by a group of linguists and technical experts from various branches of the food industry on a voluntary basis and as a public service. In the case of Chapter VIII ("Dairy Products") the translation was done by the chief supervisor of the Milk Division of the Department of Health of the City of New York.

The chairman of the drafting committee is inviting all food and cosmetic manufacturers, food technologists, and other interested parties to submit to the drafting committee, through the intermediary of The Food Law Institute, any comments and suggestions which

[4] Dr. Grau is known to the readers of this *Journal* for his article "Food Additives and Cancer" in the June, 1958 issue, at pp. 350-352.

could help to improve or implement the uniform food code or to eliminate any provisions which may be unduly restrictive or which would result in restricting United States exports of food products and cosmetics to Latin America. To the extent the drafting committee may find it possible, such comments will be incorporated in the final revised draft of the code which the committee is planning to submit to the Sixth Inter-American Chemical Congress which will take place at Mexico City, March 29-April 3, 1959. Incidentally, The Food Law Institute is planning to publish, in due course, a bilingual edition of the final draft as adopted by the Inter-American Chemical Congress.

The adoption of the draft by the Inter-American Chemical Congress—a private but very influential professional organization—will, of course, not make it automatically a part of the law of every Latin-American Republic. Also, practical considerations and differences in local conditions and customs in the various republics may make it necessary to "adapt" the model code to a certain extent to suit such local conditions in a particular country. Nevertheless, the backing of the code by the above-mentioned organization—and very probably also by the Inter-American Bar Association—will give the draft code a great deal of prestige. In addition to that, members of the health departments or other government departments of all the Latin-American republics are cooperating with the drafting committee in Buenos Aires in the preparation of the preliminary draft. The very idea of a modern and, preferably, uniform food code in Latin America is very popular in government and industrial circles. The final stage of this development—the actual enactment of the uniform food code or its adaptation—in the various republics will be one of the most important concerns of the new Food, Drug and Cosmetic Law Section of the Inter-American Bar Association, which was formed at the meeting of that association in Buenos Aires in November, 1957.

"Latin-American Drug Laws"

I would recommend to the reader the very informative article by Victor C. Folsom, published in the March, 1958 issue of the JOURNAL, pages 165 to 171. At this time I have no further developments to report.

Developments in Europe and United Nations

A report on this subject will be included in the next "Foreign Law Comment."

WASHINGTON—Continued from page 614

"A Survey of Radioactive Residue in Foods Before and After 1945: Evidence of Possible Fallout Contamination."—The text of an important report by Edwin P. Laug and Wendell C. Wallace, both of the Food and Drug Administration, follows:

"This report covers results of a survey conducted over the past two years to determine to what degree foods may have become contaminated with radioactive fallout. It has been assumed that no significant man-made radioactive contamination could have occurred prior to 1945, the year the first experimental and military nuclear devices were exploded. Foods produced before and after this critical date have therefore been examined for total radioactive content adjusted for the presence of potassium 40, a widely distributed naturally occurring radioactive isotope. It is possible that other naturally occurring radioactive substances may contribute to the total. This contribution is extremely small, and while it may vary from food to food there is no reason to expect it to vary with time. Consequently if we consider the radioactive content of all pre-'45 foods as a base line, any increase over this in food produced since 1945 can be interpreted as man-made radioactive contamination. This contamination is presently contributed mainly by fallout from weapons testing, but it can be expected also to reflect the presence of nuclear power plants and other applications.

"In January 1957, in response to an appeal by the Food and Drug Administration, nearly a thousand samples of food antedating 1945 were submitted. These foods came from private homes and the food industry; some even from the caches of the Shackleton and Byrd Antartica expeditions dating back to 1906. In addition, an equal number of post-'45 samples were collected mostly from retail outlets. The program is now current, with certain items under more intensive surveillance than others.

"The following categories were examined for total radioactivity: vegetables, fruits, fruit juices, sea foods, dairy products, bread, meat products, wheat, sugars, jams and jellies, cocoa and cocoa beans, tea. Nearly half of the samples analyzed were fruits and vegetables.

"*Results—I. Vegetables.* Analyses of the following number of samples of different vegetables, about half of each of which were produced before 1945, revealed that the post-'45 samples showed no significant increase in total radioactivity: potatoes, 29; corn, 90; beans, 132; peas, 92; beets and turnips, 40; carrots, 30; spinach, 27 and miscellaneous, 90.

"*II. Fruits.* Analyses of the following number of samples of different fruits, about half of each of which were produced before 1945, revealed that the post-'45 samples showed no significant increase in total radioactivity: pears, 48; cherries, 61; peaches, 89; apricots, 28; plums, 61; tomatoes and tomato products, 134; berries, 73; fruit juices, 78 and miscellaneous, 57.

"*III. Sea Food.* 51 samples of miscellaneous fish varieties and 32 samples of oysters and clams, half of each of which were canned after 1945, exhibited a trend toward higher radioactivity. However, individual shellfish values showed a significant rate of increase when plotted by years since 1944. Other types of sea food such as shrimp, lobster and crabs showed no trend whatsoever.

"*IV.* A number of unrelated items were also examined for total radioactivity. Analyses of the following numbers of samples revealed no increase in total radioactivity: meat products, 26; wheat, 47; sugar and jams, 38. In the case of bread where there were un-

fortunately no pre-'45 samples available there was no evidence of total radioactivity that could not be accounted for by the potassium content. On the other hand in cocoa and cocoa beans there was a radioactive content greater than could be accounted for by potassium. Without comparison with pre-'45 samples it could of course not be determined whether this excess radioactivity had been caused by fallout contamination.

"V. In consonance with the findings of other investigators, the analyses of dairy products consisting chiefly of fresh fluid milk, evaporated milk, milk powder and cheese, show a statistically significant increase in total radioactivity in those products produced since 1945.

"VI. The largest increase noted was in tea. While the examination of 36 pre-'45 samples showed no radioactivity on the average in excess of that accountable by potassium, 78 post-'45 samples chiefly from 1956 and 1957 harvests showed radioactivity that averaged about 30 times greater, with 6 individual samples ranging as high as 109 to 135 times greater. In terms of micro micro curies per kilogram of tea leaves the average value for the 78 samples was 13,500. While no specific istopes have been identified we may assume that at least 1% of this activity could potentially be Sr 90. It could therefore be possible that many of the tea samples examined contain Sr 90 in excess of the present tolerance of 80 micro micro curies per kg., but analyses of strong tea brews revealed that only about 17% of the radioactivity was extracted. It can be concluded therefore that the beverage as commonly consumed would not contain over-tolerance amounts of Sr 90.

"Conclusion.—Compared to food samples produced prior to 1945 this survey shows that the great majority of post-'45 samples do not carry significant burdens of radioactivity. Notable exceptions are certain sea foods, dairy products and tea."

Statement of Policy—Incubator Reject Eggs.—The following statement of policy became effective on September 5, 1958:

"Investigations by the Food and Drug Administration and a number of State regulatory agencies have revealed that incubator reject eggs, removed as infertile or otherwise unhatchable during hatching operations, are being diverted for human food use. Such eggs are regarded as adulterated within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1046; 21 U. S. C. 342(a)(3)) because they are unfit for food.

". . . The introduction or delivery for introduction into interstate commerce of adulterated eggs is prohibited under section 301(a) of the aforesaid act (52 Stat. 1042; 21 U. S. C. 331(a)) unless they have been broken, crushed, or smashed and then denatured with kerosene, creolin, or other suitable denaturant to preclude their diversion to human food channels."—Reported in CCH FOOD DRUG COSMETIC LAW REPORTS, ¶ 1205 (October 9, 1958).

Application of Cosmetics-Labeling Requirements to Certain Detergents Other than Soap.—Effective September 26, 1958, according to an FDA statement of interpretation, detergent substances other than soap, intended for use in cleansing the body, are subject to the labeling requirements prescribed for cosmetics: "Products intended for cleansing the human body and which are not "soap" as set out . . . are "cosmetics," and accordingly they are subject to the requirements of the act and the regulations thereunder. For example, such a product in bar form is subject to the requirement, among others, that it shall bear a label containing an accurate statement of the weight of the bar in avoirdupois pounds and ounces, this statement to be prominently and conspicuously displayed so as to be likely to be read under the customary conditions of purchase and use."—Reported in CCH FOOD DRUG COSMETIC LAW REPORTS, ¶ 1285.02 (October 9, 1958).

STATE

FOOD AND DRUG NOTES

Florida.—Recently, in an opinion addressed to the state commissioner of agriculture by Attorney General Richard W. Ervin and Assistant Attorney General T. Paine Kelly, it was held that a food or drink which contained an artificial sweetener but which was not intended by the manufacturer for sale as a special dietary food was not required to be sold as such. The presence of an artificial sweetener in food or drink does not necessarily make that food or drink one for "special dietary use," and thus subject to the provisions of Section 500.25(1), Florida Statutes, requiring the grouping of such foods at a separate space or location in all retail establishments, with special marking indicating that they are "special dietary foods."

The opinion concluded:

"Artificial sweeteners, colorings and flavors are universally considered nonnutritive and non-deleterious substitutes. Any administrative rule or regulation requiring the designation of the subject project [product] under discussion would be subject to criticism upon the grounds of unreasonableness, discrimination and caprice."

North Carolina.—An opinion by Attorney General Malcolm B. Seawell and Assistant Attorney General Ralph Moody, addressed to North Carolina's agriculture commissioner, deemed a milk-carton label bearing the name of a supermarket violative of the North Carolina statute outlawing "false or misleading labeling," since an ordinary person would think that the milk was processed, produced and distributed by the supermarket itself. The fact that it was processed and filled by a named dairy appeared in insignificant, small type at the bottom of the carton.

Also, an ice cream carton labeled ". . . Company" was misleading, since it would lead the ordinary person to believe that the named company had produced and manufactured the ice cream when, in fact, the ice cream had been procured from various processors. The carton did not bear the name or address of any manufacturer, producer or processor.

Similarly violative of the statute was an ice cream carton intended for retail distribution in supermarkets and stores, the labeling of which indicated in very small type the name and location of the manufacturer. It was, therefore, misleading, since the same brand for ice cream was used by two other companies. The name of the manufacturer should have been more prominent, so that the public would definitely have known whose ice cream it was and also that it was not processed by some distributor.

Other ice cream cartons, with an out-of-state general office address, comply with the labeling laws, provided that a code number appears on the carton to indicate the specific plant in which the ice cream was manufactured or processed. The opinion pointed out that this would be true regardless of whether the ice cream was manufactured in North Carolina or out of North Carolina.

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